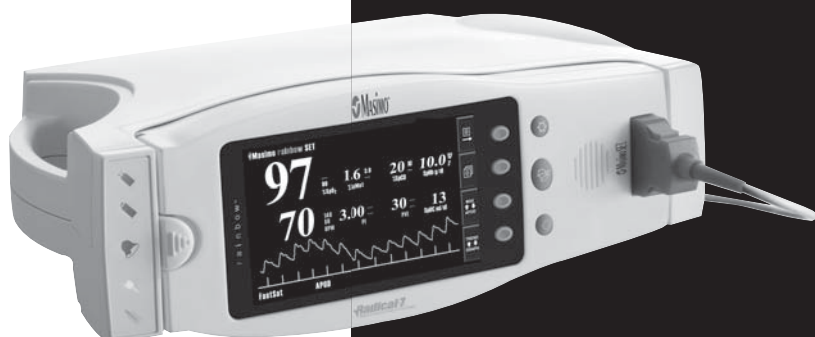


# **Radical-7™**

**Signal Extraction  
with Rainbow  
OPERATOR'S**

**Pulse CO-Oximeter  
Technology  
MANUAL**





**Signal Extraction Pulse CO-Oximeter**

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**OPERATOR'S MANUAL**

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The Radical-7 Pulse CO-Oximeter Operating Instructions provide the necessary information for proper operation of all models of the Radical-7 Pulse CO-Oximetry system. There may be information provided in this manual that is not relevant for your system.

General knowledge of pulse oximetry and an understanding of the features and functions of the Radical-7 Pulse CO-Oximeter are prerequisites for its proper use.

Do not operate the Radical-7 Pulse CO-Oximeter without completely reading and understanding the instructions in this manual.

**NOTICE:**

Purchase or possession of this instrument does not carry any express or implied license to use this instrument with replacement parts which would, alone or in combination with this instrument, fall within the scope of one of the patents relating to this instrument.

**CAUTION:**

Federal law (U.S.) restricts this instrument to sale by or on the order of a physician.

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80fk

MEDICAL ELECTRICAL EQUIPMENT WITH RESPECT TO ELECTRIC  
SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH  
UL 60601-1/CAN/CSA C22.2 No. 601.1

Covered by one or more of the following U.S. Patents: RE38492, RE38476, 7530955, 7509154, 7499741, 7496393, 7489958, 7471969, 7469157, 7467002, 7377899, 7376453, 7373194, 7355512, 7328053, 7295866, 7254433, 7221971, 7215986, 7467002, 7377899, 7376453, 7373194, 7355512, 7328053, 7295866, 7254433, 7221971, 7215986, 6699194, 6684090, 6658276, 6654624, 6650917, 6643530, 6606511, 6584336, 6515273, 6501975, 6463311, 6430525, 6388240, 6360114, 6263222, 6236872, 6229856, 6157850, 6067462, 6011986, 6002952, 5919134, 5769785, 5758644, 5685299, international equivalents, or one or more of the patents referenced at [www.masimo.com/patents.htm](http://www.masimo.com/patents.htm). Products containing SatShare® feature are also covered by U.S. Patent 6,770,028. Other patents pending.

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## **NON-INVASIVE TOTAL HEMOGLOBIN (SpHb) ACCURACY COMPARED TO INVASIVE LABORATORY METHODS\***

In 492 comparisons of non-invasive total hemoglobin (SpHb) and invasive hemoglobin (tHb) measurements from a laboratory CO-Oximeter, SpHb accuracy was as follows:

- 0.90 correlation
- 0.95 g/dL standard deviation
- Below 12 g/dL, 99% of SpHb readings were < 2 g/dL of the laboratory tHb value
- At or above 12 g/dL, 94% of SpHb readings were < 2 g/dL of the laboratory value

\* Masimo FDA Submission Data

## **SAFETY INFORMATION, WARNINGS, CAUTIONS AND NOTES**

The Radical-7 Signal Extraction Pulse CO-Oximeter is designed to minimize the possibility of hazards from errors in the software program by following sound engineering design processes, Risk Analysis and Software Validation.

- The Radical-7 is to be operated by qualified personnel only. This manual, accessory Directions for Use (DFU), all precautionary information, and specifications should be read before use.
- Variation in hemoglobin measurements may be profound and may be affected by sample type, body positioning, as well as other physiological conditions. As with most hemoglobin tests, Radical-7 test results should be scrutinized in light of a specific patient's condition. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data.
- Explosion hazard. Do not use the Radical-7 in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- Electric shock hazard. Do not open the Radical-7 cover except to replace the battery of the Handheld instrument. Only a qualified operator may perform maintenance procedures specifically described in this manual. Refer servicing to Masimo for repair of this equipment.
- High intensity, extreme lights (including pulsating strobe lights) directed on the sensor may not allow the Radical-7 to obtain readings.
- The Radical-7 should be considered an early warning instrument. As a trend towards patient hypoxemia is indicated, blood samples should be analyzed by laboratory instruments to completely understand the patient's condition.
- If patient hypoxemia is indicated, blood samples should be analyzed by laboratory devices to completely understand the patient's condition.
- The Radical-7 is NOT intended for use as an apnea monitor.
- Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The Radical-7 should not be used as a replacement or substitute for ECG based arrhythmia analysis.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Do not place the Radical-7 or accessories in any position that might cause it to fall on the patient. Do not lift the Pulse CO-Oximeter by the power cord or any other cable.

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## SAFETY INFORMATION, WARNINGS, CAUTIONS AND NOTES (CONTINUED)

- Patient Safety - If a sensor is damaged in any way, discontinue use immediately.
- Always remove the sensor from the patient and completely disconnect the patient from the Radical-7 before bathing the patient.
- Interfering Substances: Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.
- Do not use the Radical-7 or sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The Radical-7 may affect the MRI image, and the MRI instrument may affect the accuracy of the Radical-7 parameters and measurements.
- The Radical-7 can be used during defibrillation, but the readings may be inaccurate for up to 20 seconds.
- If using Radical-7 during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the instrument might read zero for the duration of the active radiation period.
- Do not place the Radical-7 where the controls can be changed by the patient.
- Do not place the Radical-7 on electrical equipment that may affect the Radical-7, preventing it from working properly.
- Do not expose the Radical-7 to excessive moisture such as direct exposure to rain. Excessive moisture can cause the Radical-7 to perform inaccurately or fail.
- Do not place containers with liquids on or near the Radical-7. Liquids spilled on the Pulse CO-Oximeter may cause it to perform inaccurately or fail.
- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- SpO<sub>2</sub> is empirically calibrated to functional arterial oxygen saturation in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb). The Radical-7 can not measure elevated levels of COHb or MetHb. Increases in either COHb or MetHb will affect the accuracy of the SpO<sub>2</sub> measurement.
- Inaccurate SpO<sub>2</sub> readings can be caused by:
  - Elevated levels of COHb and MetHb
    - For increased COHb: COHb levels above normal tend to increase the level of SpO<sub>2</sub>. The level of increase is approximately equal to the amount of COHb that is present.

**NOTE:** High levels of COHb may occur with a seemingly normal SpO<sub>2</sub>. When elevated levels of COHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
    - For increased MetHb: the SpO<sub>2</sub> may be decreased by levels of MetHb of up to approximately 10% to 15%. At higher levels of MetHb, the SpO<sub>2</sub> may tend to read in the low to mid 80s. When elevated levels of MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
  - Intravascular dyes such as indocyanine green or methylene blue.
  - Externally applied coloring (such as nail polish).
  - Elevated levels of Bilirubin

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## **SAFETY INFORMATION, WARNINGS, CAUTIONS AND NOTES (CONTINUED)**

- Severe anemia
- Low arterial perfusion
- Motion artifact
- Inaccurate SpHb and SpOC readings can be caused by:
  - Intravascular dyes such as indocyanine green or methylene blue
  - Externally applied coloring (such as nail polish)
  - Elevated levels of Bilirubin
  - Low arterial perfusion
  - Motion artifact
  - Low arterial oxygen saturation levels
  - Hemoglobin synthesis disorders
  - Hemoglobinopathy
  - Peripheral vascular disease
  - EMI radiation interference
- Inaccurate SpCO and SpMet readings can be caused by:
  - Elevated levels of Bilirubin
  - Motion artifact
  - Low arterial oxygen saturation levels
- Do not place the Radical-7 against a surface. This can cause a system or battery (non-clinical) alarm to be muffled.
- For home use, ensure that the Radical-7's alarm can be heard from other rooms in the house, especially when noisy appliances such as vacuum cleaners, dishwashers, clothes dryers, televisions, or radios are operating.
- Additional information specific to Masimo sensors, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's Directions for Use (DFU).
- If the Radical-7 fails any part of the setup procedures or leakage tests, remove the Radical-7 from operation until qualified service personnel have corrected the situation.
- Do not incinerate battery.
- Disposal of product - Comply with local laws in the disposal of the instrument and/or its accessories.
- To protect against injury from electric shock, follow the directions below:
  - Do not place the instrument near water.
  - Avoid placing the instrument on surfaces with visible liquid spills.
  - Do not soak or immerse the instrument in liquids.
  - Always turn off and disconnect the power cord from the AC power supply before cleaning the instrument.
  - Use cleaning solutions sparingly.
- This equipment has been tested and found to comply with the limits for medical instruments to the EN 60601-1-2: 2002, Medical Instrument Directive 93/42/EEC. These limits are

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## SAFETY INFORMATION, WARNINGS, CAUTIONS AND NOTES (CONTINUED)

designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other instruments in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other instruments, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving instrument.
  - Increase the separation between the equipment.
  - Connect the equipment into an outlet on a circuit different from that to which the other instrument(s) are connected.
  - Consult the manufacturer for help.
- To ensure safety, avoid stacking multiple instruments or placing anything on the instrument during operation.
- Cleared Use Only: The device and related accessories are cleared by the Food and Drug Administration (FDA) for noninvasive patient monitoring and may not be used for any processes, procedures, experiments or any other use for which the device is not intended or cleared by the FDA, or in any manner inconsistent with the instructions for use or labeling. This device and related accessories are not intended for use in combination with any other medical devices or in high-risk applications.





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## About This Manual

This manual explains how to set up and use the Radical-7™ Pulse CO-Oximeter containing Masimo Rainbow® SET® technology. Important safety information relating to general use of the Pulse CO-Oximeter appears before this introduction. Other important safety information is located throughout the manual where appropriate.

***Read the entire safety information section before you operate the monitor.***

In addition to the safety section, this manual includes the following sections:

- |                   |   |
|-------------------|---|
| <b>SECTION 1</b>  | <b>OVERVIEW</b> gives a general description of Radical-7 Pulse CO-Oximeter.   |
| <b>SECTION 2</b>  | <b>SYSTEM DESCRIPTION</b> describes the Radical-7 Pulse CO-Oximeter system and its functions and features.  |
| <b>SECTION 3</b>  | <b>SETUP</b> describes how to setup the Radical-7 Pulse CO-Oximeter for use.  |
| <b>SECTION 4</b>  | <b>OPERATION</b> describes the operation of the Radical-7 Pulse CO-Oximetry system.   |
| <b>SECTION 5</b>  | <b>ALARMS AND MESSAGES</b> describes the alarm system messages.   |
| <b>SECTION 6</b>  | <b>TROUBLESHOOTING</b> describes troubleshooting information.   |
| <b>SECTION 7</b>  | <b>SPECIFICATIONS</b> gives the detailed specifications of the Radical-7 Pulse CO-Oximeter.   |
| <b>SECTION 8</b>  | <b>SENSORS &amp; PATIENT CABLES</b> outlines how to use and care for Masimo Rainbow SET technology sensors, Masimo Rainbow SET technology patient cables, Masimo Red sensors and Masimo Red patient cables. |
| <b>SECTION 9</b>  | <b>SERVICE AND MAINTENANCE</b> describes how to maintain, service and obtain repair for the Radical-7 Pulse CO-Oximeter.  |
| <b>SECTION 10</b> | <b>ACCESSORIES</b> lists the available Radical-7 Pulse CO-Oximeter accessories.   |

## Warnings, Cautions and Notes

Please read and follow any warnings, cautions and notes presented throughout this manual. An explanation of these labels are as follows:

A **WARNING** is provided when actions may result in a serious outcome (i.e., injury, serious adverse affect, death) to the patient or user. Look for text in a gray shaded box.

Sample of Warning:

**WARNING:** THIS IS A SAMPLE OF A WARNING STATEMENT.

A **CAUTION** is given when any special care is to be exercised by the patient or user to avoid injury to the patient, damage to this instrument or damage to other property.

Sample of Caution:

**CAUTION:** THIS IS A SAMPLE OF A CAUTION STATEMENT.

A **NOTE** is provided when extra general information is applicable.

Sample of Note:

**NOTE:** *This is a sample of a Note.*

## Product Description

The Radical-7 Pulse CO-Oximeter is a noninvasive, arterial oxygen saturation, total hemoglobin concentration and pulse rate monitor. The Radical-7 Pulse CO-Oximeter can be used as either a Handheld or a Standalone monitor. The Radical-7 Pulse CO-Oximeter features a backlit Liquid Crystal Display (LCD) that continuously displays numeric values for SpO<sub>2</sub>, SpMet<sup>®</sup>, SpCO<sup>®</sup>, SpHb<sup>®</sup>, SpOC<sup>™</sup>, pulse rate, Perfusion Index (PI) and Pleth Variability Index (PVI). It also provides graphical displays for plethysmographic waveform, Signal Identification and Quality Indicator (Signal IQ<sup>®</sup>). The Radical-7 Pulse CO-Oximeter can be used to interface with a multiparameter patient monitor to provide Masimo SET SpO<sub>2</sub> and pulse rate information to that monitor for display.

## FEATURES

These features are common to the Radical-7 family:

- Masimo SET is clinically proven to be the highest sensitivity and specificity pulse oximeter technology in the world.
- Rainbow technology uses 7+ wavelengths of light to continuously and noninvasively measure carboxyhemoglobin (SpCO<sup>®</sup>), methemoglobin (SpMet<sup>™</sup>\*) and total hemoglobin (SpHb<sup>™</sup>), as well as providing a more reliable probe-off detection.
- Total Oxygen Content (SpOC<sup>™</sup>\*) provides a calculated measurement of the amount of oxygen in arterial blood, which may provide useful information about oxygen both dissolved in plasma and combined with hemoglobin.
- Perfusion Index (PI) with trending capability indicates arterial pulse signal strength and may be used as a diagnostic tool during low perfusion.
- \*Pleth Variability Index (PVI) may show changes that reflect physiologic factors such as vascular tone, circulating blood volume, and intrathoracic pressure excursions.<sup>1</sup>
- Accurate on cyanotic infants with congenital heart disease when used with an LNOP<sup>®</sup> Blue Sensor.
- Signal IQ<sup>®</sup> waveform for signal identification and quality indication during excessive motion and low signal to noise situations.
- FastSat<sup>®</sup> tracks rapid changes in arterial O<sub>2</sub> with high fidelity unlike any other pulse oximeter.
- Variable pitch provides tonal variance for every 1% change in saturation.
- SatShare<sup>®</sup> interface allows transfer of SpO<sub>2</sub> and pulse rate to an existing multiparameter monitor and allows for the reading of SpCO, SpMet, SpHb and SpOC on the Radical-7 monitor.
- Automatic screen rotation provides upright display for vertical or horizontal monitor positioning.
- Remote alarming interface.
- Trend Auto Scale feature.
- Detachable portable handheld for patient transport.
- \*3D ALARM<sup>™</sup>
  - Desat Index Alarm<sup>™</sup> enables clinicians to detect an increasing quantity of smaller desaturations that may precede declining respiratory status.
  - PI Delta Alarm<sup>™</sup> alerts clinicians to possible changes in perfusion, often a reliable indicator of illness severity.

<sup>1</sup> The utility of PVI is unknown at this time and requires further clinical studies. Technical factors that may affect PVI include probe malposition and patient motion.

\* Optional parameters/measurements

## INDICATIONS FOR USE

The Radical-7 Pulse CO-Oximeter and accessories are indicated for the continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>), pulse rate (measured by a SpO<sub>2</sub> sensor), carboxyhemoglobin and methemoglobin concentrations expressed in percentage (SpCO and SpMet) and total hemoglobin concentration expressed in grams per deciliter (SpHb). The Radical-7 Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric and neonatal patients during both motion and no motion conditions, who are well or poorly perfused patients in hospitals, hospital-type facilities, mobile and home environments.

## Pulse CO-Oximetry

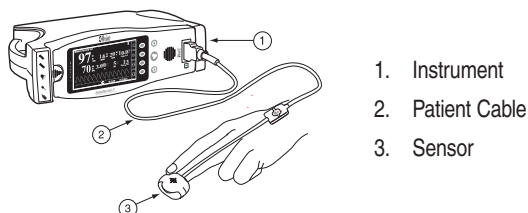
### SpO<sub>2</sub> GENERAL DESCRIPTION

Pulse CO-Oximetry is a continuous and noninvasive method of measuring the level of arterial oxygen saturation in blood. The measurement is taken by placing a sensor on a patient, usually on the fingertip for adults and the hand or foot for neonates. The sensor is connected to the Pulse CO-Oximetry instrument with a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data in three ways:

1. As a percent value for arterial oxygen saturation (SpO<sub>2</sub>)
2. As a pulse rate (PR)
3. As a plethysmographic waveform

The following figure shows the general monitoring setup.

### SpCO GENERAL DESCRIPTION



Pulse CO-Oximetry is a continuous and noninvasive method of measuring the levels of carbon monoxide concentration (SpCO) in arterial blood. It relies on the same basic principles of pulse oximetry (spectrophotometry) to make its SpCO measurement. The measurement is obtained by placing a sensor on a patient, usually on the fingertip for adults and the hand or foot for infants. The sensor connects either directly to the Pulse CO-Oximetry instrument or through a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data as percentage value for the SpCO, which reflect blood levels of carbon monoxide bound to hemoglobin.

### SpMet GENERAL DESCRIPTION

Pulse CO-Oximetry is a continuous and noninvasive method of measuring the levels of methemoglobin concentration (SpMet) in arterial blood. It relies on the same basic principles of pulse oximetry (spectrophotometry) to make its SpMet measurement. The measurement is obtained by placing a sensor on a patient, usually on the fingertip for adults and the hand or foot for infants. The sensor connects either directly to the Pulse CO-Oximetry instrument or



through a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data as percentage value for the SpMet.

### SpHb GENERAL DESCRIPTION

Pulse CO-Oximetry is a continuous and non-invasive method of measuring the levels of total hemoglobin (SpHb) in arterial blood. It relies on the same principles of pulse oximetry to make the SpHb measurement. The measurement is taken by a sensor capable of measuring SpHb, usually on the fingertip for adult and pediatric patients. The sensor connects directly to the Pulse CO-Oximeter or with a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data as measurement of total hemoglobin concentration.

### TOTAL ARTERIAL OXYGEN CONTENT (CaO<sub>2</sub>) GENERAL DESCRIPTION <sup>2</sup>

Oxygen (O<sub>2</sub>) is carried in the blood in two forms, either dissolved in plasma or combined with hemoglobin. The amount of oxygen in the arterial blood is termed the oxygen content (CaO<sub>2</sub>) and is measured in units of ml O<sub>2</sub>/dl blood. One gram of hemoglobin (Hb) can carry 1.34 ml of oxygen, whereas 100 ml of blood plasma may carry approximately 0.3 ml of oxygen. The oxygen content is determined mathematically as:

$$\text{CaO}_2 = 1.34 (\text{ml O}_2/\text{g Hb}) \times \text{Hb (g/dl)} \times \text{HbO}_2 + \text{PaO}_2 (\text{mm Hg}) \times (0.3 \text{ ml O}_2 / 100 \text{ mm Hg/dl})$$

Where HbO<sub>2</sub> is the fractional arterial oxygen saturation and PaO<sub>2</sub> is the partial pressure of arterial oxygen.

For typical PaO<sub>2</sub> values, the second part of the above equation [PaO<sub>2</sub> (mm Hg) x (0.3 ml O<sub>2</sub> / 100 mm Hg/dl)] is approximately 0.3 ml/dl. Furthermore, for typical carboxyhemoglobin and methemoglobin levels, the functional saturation (SpO<sub>2</sub>) as measured by a pulse oximeter is given by:

$$\text{SpO}_2 = 1.02 \times \text{HbO}_2$$

<sup>2</sup> Martin, Laurence. *All You Really Need to Know to Interpret Arterial Blood Gases, Second Edition*. New York: Lippincott Williams & Wilkins, 1999.

### SpOC General Description (Pulse CO-Oximetry)

The above approximations result in the following reduced equation for oxygen content via the Pulse CO-Oximeter:

$$\text{SpOC (ml/dl}^*) = 1.31 (\text{ml O}_2/\text{g Hb}) \times \text{SpHb (g/dl)} \times \text{SpO}_2 + 0.3 \text{ ml/dl}$$

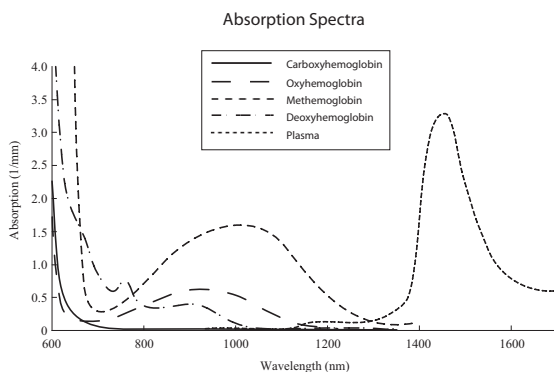
\* When ml O<sub>2</sub>/g Hb is multiplied by g/dl of SpHb, the gram unit in the denominator of ml/g cancels the gram unit in the numerator of g/dl resulting in ml/dl (ml of oxygen in one dl of blood) as the unit of measure for SpOC.

### PRINCIPLE OF OPERATION

1. Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxygenated blood), carboxyhemoglobin (blood with carbon monoxide content), methemoglobin (blood with oxidized hemoglobin) and blood plasma constituents differ in their absorption of visible and infrared light (using spectrophotometry).
2. The amount of arterial blood in tissue changes with your pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

The Radical-7 Pulse CO-Oximeter uses a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, oxidized blood and blood plasma. The Radical-7 utilizes a sensor with various light-emitting diodes (LEDs) that pass

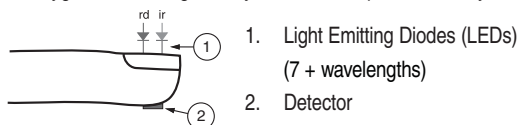
light through the site to a diode (detector). Signal data is obtained by passing various visible and infrared lights (LEDs, 500 to 1400nm) through a capillary bed (for example, a fingertip, a hand, a foot) and measuring changes in light absorption during the blood pulsatile cycle. This information may be useful to clinicians. The maximum radiant power of the strongest light is rated at  $\leq 25$  mW. The detector receives the light, converts it into an electronic signal and sends it to the Radical-7 for calculation.



Once the Radical-7 receives the signal from the sensor, it utilizes Masimo Rainbow SET signal extraction technology to calculate the patient's functional oxygen saturation ( $\text{SpO}_2$  (%)), blood levels of carboxyhemoglobin ( $\text{SpCO}$  (%)), methemoglobin ( $\text{SpMet}$  (%)), Total Hemoglobin concentration ( $\text{SpHb}$  (g/dl)) and pulse rate (PR (BPM)). The  $\text{SpCO}$ ,  $\text{SpMet}$  and  $\text{SpHb}$  measurements rely on a multiwavelength calibration equation to quantify the percentage of carbon monoxide and methemoglobin and the concentration of total hemoglobin in arterial blood. In an ambient temperature of  $35^\circ\text{C}$  the maximum skin surface temperature has been measured at less than  $106^\circ\text{F}$  ( $41^\circ\text{C}$ ), verified by Masimo sensor skin temperature test procedure.

## FUNCTIONAL SATURATION

The Radical-7 is calibrated to measure and display functional saturation ( $\text{SpO}_2$ ): the amount of oxyhemoglobin expressed as a percentage of the hemoglobin that is available to transport oxygen. Note that carboxyhemoglobin is not capable of transporting oxygen, but is recognized as oxygenated hemoglobin by conventional pulse oximetry.



## RADICAL-7 vs. DRAWN WHOLE BLOOD MEASUREMENTS

When  $\text{SpO}_2$ ,  $\text{SpCO}$ ,  $\text{SpMet}$  and  $\text{SpHb}$  measurements obtained from the Radical-7 (non-invasive) are compared to drawn whole blood (invasive) measurements by blood gas and/or laboratory CO-Oximetry methods, caution should be taken when evaluating and interpreting the results. The blood gas and/or laboratory CO-Oximetry measurements may differ from the  $\text{SpO}_2$ ,  $\text{SpCO}$ ,  $\text{SpMet}$ ,  $\text{SpHb}$  and  $\text{SpOC}$  measurements of the Radical-7 Pulse CO-Oximeter. In the case of  $\text{SpO}_2$ , different results are usually obtained from the arterial blood gas sample if the calculated measurement is not appropriately corrected for the effects of variables that shift the relationship between the partial pressure of oxygen ( $\text{PO}_2$ ) and saturation, such as: pH,

temperature, the partial pressure of carbon dioxide ( $PCO_2$ ), 2,3-DPG, and fetal hemoglobin. In the case of  $SpCO$ , different results are also expected if concentration of methemoglobin in the blood gas sample is abnormal (greater than 2% for methemoglobin concentration). High levels of bilirubin may cause erroneous  $SpO_2$ ,  $SpMet$ ,  $SpCO$  and  $SpHb$  readings. As blood samples are usually taken over a period of 20 seconds (the time it takes to draw the blood) a meaningful comparison can only be achieved if the oxygen saturation, carboxyhemoglobin and methemoglobin concentration of the patient are stable and not changing over the period of time that the blood gas sample is taken. Subsequently, blood gas and laboratory CO-Oximetry measurements of  $SpO_2$ ,  $SpCO$ ,  $SpMet$ ,  $SpHb$  and  $SpOC$  may vary with the rapid administration of fluids and in procedures such as dialysis. Additionally, drawn, whole-blood testing can be affected by sample handling methods and time elapsed between blood draw and sample testing.

## **SIGNAL EXTRACTION TECHNOLOGY (SET)**

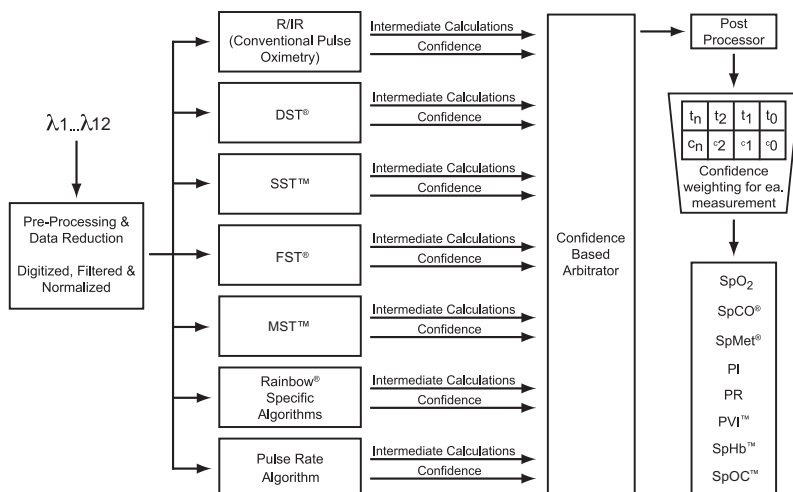
Masimo Signal Extraction Technology's signal processing differs from that of conventional pulse oximeters. Conventional pulse oximeters assume that arterial blood is the only blood moving (pulsating) in the measurement site. During patient motion, however, the venous blood also moves, causing conventional pulse oximeters to read low values, because they cannot distinguish between the arterial and venous blood movement (sometimes referred to as noise). Masimo SET pulse oximetry utilizes parallel engines and adaptive digital filtering. Adaptive filters are powerful because they are able to adapt to the varying physiologic signals and/or noise and separate them by looking at the whole signal and breaking it down to its fundamental components. The Masimo SET signal processing algorithm, Discrete Saturation Transform® (DST®), in parallel with Fast Saturation Transform® (FST®), reliably identifies the noise, isolates it and, using adaptive filters, cancels it. It then reports the true arterial oxygen saturation for display on the monitor.

## SpCO, SpMet AND SpHb MEASUREMENTS DURING PATIENT MOTION

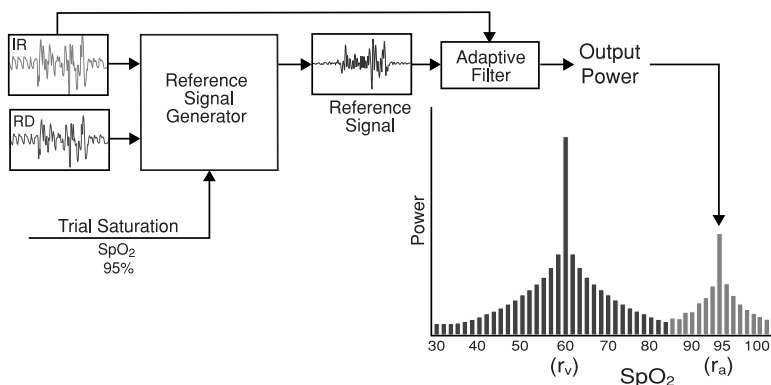
The Radical-7 displays measurements of SpCO, SpMet and SpHb during patient motion. However, because of the changes in the physiological parameters such as blood volume, arterial-venous coupling, etc. that occur during patient motion, the accuracy of such measurements may not be reliable during excessive motion. The measurements for SpCO, SpMet and SpHb display “...” and a message, “LOW SpCO SIQ”, “LOW SpMet SIQ” or “LOW SpHb SIQ”, displays to alert the clinician that the instrument does not have confidence in the value due to poor signal quality caused by excessive motion or other signal interference.

## MASIMO RAINBOW SET PARALLEL ENGINES

This figure is for conceptual purposes only.



## MASIMO SET DST<sup>®</sup>



## Introduction

The Radical-7 provides the functionality of three instruments in one:

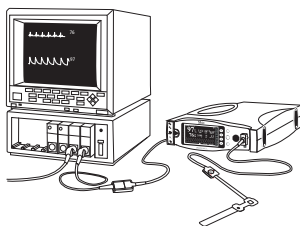
- The Radical-7 is a fully featured Handheld Pulse CO-Oximeter.
- The Radical-7 is a fully featured Standalone Pulse CO-Oximeter.
- The Radical-7 interfaces to the SpO<sub>2</sub> input module of multiparameter patient monitors\* to upgrade conventional pulse oximetry technology to Masimo SET technology.



The Handheld portion of the Radical-7 contains the majority of the Pulse CO-Oximeter features. All pulse co-oximetry measurement information, as well as instrument status data is displayed on the Handheld LCD screen. All user input is performed through the control buttons on the front panel. The sensor cable connector is located on the Radical-7 Handheld Pulse CO-Oximeter.



The Handheld Pulse CO-Oximeter snaps into the Radical Docking Station to provide a fully featured standalone Pulse CO-Oximeter. The Docking Station connects to AC power for standalone operation or charging of the Handheld. An optional Docking Station battery is available. The standalone Radical-7 features nurse call, analog output and interfaces to serial printers.



Utilizing a SatShare® cable, the standalone Radical-7 also interfaces with the SpO<sub>2</sub> input of a validated multiparameter patient monitor\*, instantly upgrading the conventional pulse co-oximetry to Masimo SET pulse oximetry. The SatShare cable attaches to the back of the Radical Docking Station, and SatShare cables are available to interface with most multiparameter patient monitors\*.

### CAUTION:

- THE WAVEFORM DISPLAYED ON THE MULTIPARAMETER PATIENT MONITOR IS A SIMULATED SIGNAL (NON-NORMALIZED). REFER TO THE RADICAL-7 PULSE CO-OXIMETER DISPLAY FOR PATIENT WAVEFORM.
- IF DISPLAYING THE SIMULATED WAVEFORM IS NOT DESIRABLE, IT IS RECOMMENDED TO TURN OFF THE PLETHYSMOGRAPHIC WAVEFORM DISPLAY ON THE MULTIPARAMETER MONITOR.
- ONLY USE A SATSHARE CABLE THAT HAS A FERRITE BEAD INSTALLED.
- ONLY SpO<sub>2</sub> AND PULSE RATE CAN BE DISPLAYED ON THE MULTIPARAMETER MONITOR WITH SATSHARE.

Refer to Section 3, SatShare Setup and Section 4, SatShare Operation for additional details.

\*Contact Masimo for the latest list of SatShare validated multiparameter monitors.

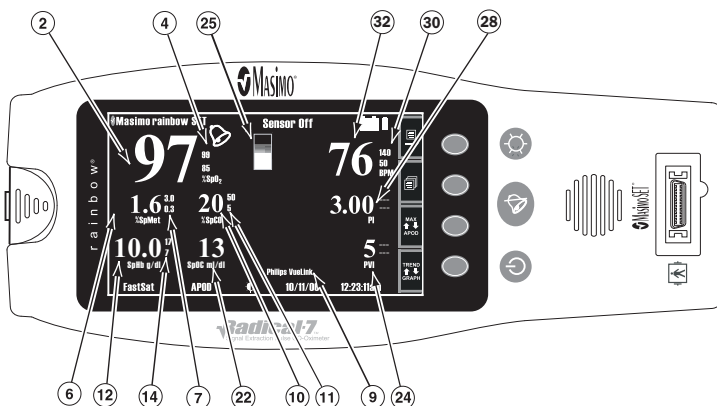
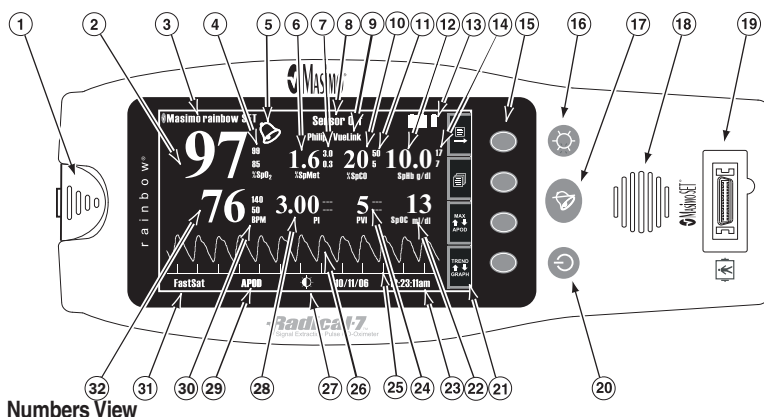
## Radical-7 Pulse CO-Oximeter Handheld

The Handheld Radical-7 Pulse CO-Oximeter provides most of the functionality of the Pulse CO-Oximeter. All user input and displays are controlled by this part of the Radical-7 Pulse CO-Oximeter system. The patient cable connects into the connector on the Handheld instrument. The Handheld is battery powered and can be used either as a transport monitor or as a Handheld Pulse CO-Oximeter for spot checks.


### HANDHELD FRONT PANEL

The following figure and corresponding text outline all the features of the Handheld Radical-7 Pulse CO-Oximeter:

#### Pleth + Signal IQ View











## HANDHELD FRONT PANEL (CONTINUED)

①		<b>HANDHELD RELEASE BUTTON</b>	Press down the Handheld Release Button and pull the Handheld instrument off the Docking Station.
②	97	<b>SpO<sub>2</sub> MEASUREMENT DISPLAY</b>	The functional arterial hemoglobin oxygen saturation is displayed in units of percentage SpO <sub>2</sub> . The upper and lower SpO <sub>2</sub> alarm limits are also displayed next to the SpO <sub>2</sub> measurement. When a sensor is not connected to a patient and during pulse search, the display will show dashed lines and the message "Sensor Off" will appear at the top of the display screen. When the measured value is outside of the alarm limits, the SpO <sub>2</sub> measurement display flashes and an alarm will sound. The oxygen saturation is calculated and the display is updated at a frequency of once per second.
③	Masimo Rainbow SET	<b>MASIMO SET OR MASIMO RAINBOW SET</b>	The Masimo SET or Masimo rainbow SET label is shown on the Radical-7 display when either SET processing is active. <b>NOTE:</b> Patient information, not SET activity, will be displayed when using a RadNet® compatible instrument connected to a monitoring system.
④	99 85	<b>SATURATION ALARM LIMITS DISPLAY</b>	The Saturation Alarm Limits Display shows the upper and lower saturation alarm limits. When an alarm limit is exceeded, the SpO <sub>2</sub> value and the violated limit flashes.
⑤		<b>ALARM STATUS INDICATOR</b>	The alarm status indicator (a bell) can be shown with or without a slash. It flashes when an alarm condition is present. When the alarm is silenced using the Alarm Silence Button, an alarm status indicator with a slash and a timer is shown to indicate that the alarm is temporarily silenced. When the alarm is silenced through the All Mute menu selection (which is permanent until power is cycled or deselected using the menu), or when the Interface Alarm SpO <sub>2</sub> /BPM is set to "No", an alarm status indicator with a slash is shown to indicate the alarm has been silenced.
⑥	1.6	<b>SpMet* MEASUREMENT DISPLAY</b>	The measurement of methemoglobin concentration levels is displayed in units of percentage SpMet. The upper and lower SpMet alarm limits are also displayed next to the SpMet measurement. When a sensor is not connected to a patient and during pulse search, the display will show dashed lines and the message "Sensor Off" will appear at the top of the display screen. The methemoglobin is calculated and the display is updated at a frequency of once per second.
⑦	3.0 0.3	<b>SpMet ALARM LIMITS DISPLAY</b>	The SpMet Alarm Limits Display shows the upper and lower alarm limits. When the measured value is outside of the alarm limits, the SpMet measurement display flashes and an alarm will sound.
⑧	Sensor Off	<b>SYSTEM MESSAGE AREA</b>	The system messages generated by the instrument are displayed in the System Message Area. See Section 5, <i>System Messages</i> .
⑨	Philips VueLink	<b>SERIAL OUTPUT MODE</b>	The Serial Output Mode displays the selected output interface with the Docking Station is connected to an external instrument via the serial port. During SatShare, the Output Mode will display the type of SatShare cable.
⑩	20	<b>SpCO* MEASUREMENT DISPLAY</b>	The measurement of carbon monoxide concentration levels is displayed in units of percentage SpCO. When a sensor is not connected to a patient and during pulse search, the display will show dashed lines and the message Sensor Off will appear at the top of the display screen. The carboxyhemoglobin is calculated and the display is updated at a frequency of once per second.

\* For instruments that include SpMet, SpCO and SpHb parameters: the SpMet, SpCO, SpHb and SpOC parameters/measurements will be dimly lit in the display screen if a patient cable is not attached or a non-Rainbow sensor is being used.

**NOTE:** The Pulse CO-Oximeter display view will be different without the optional SpCO, SpMet and SpHb parameters/measurements.

## HANDHELD FRONT PANEL (CONTINUED)




⑪	<b>50 5</b>	<b>SpCO ALARM LIMITS DISPLAY</b>	The SpCO Alarm Limits Display shows the upper and lower alarm limits. When the measured value is outside of the alarm limits, the SpCO measurement display flashes and an alarm will sound.
⑫	<b>10.0</b>	<b>SpHb* MEASUREMENT DISPLAY</b>	The measurement of total hemoglobin concentration levels is displayed in units of grams per deciliter (g/dL) or millimoles per liter (mmol/L). The upper and lower SpHb alarm limits are also displayed next to the SpHb measurement. When a sensor capable of reading SpHb is not connected to a patient and during pulse search, the display will show dashed lines and the message "Sensor Off" will appear at the top of the display screen. The display will show dashed lines during pulse search. The total hemoglobin is calculated and the display is updated at a frequency of once per second.
⑬		<b>BATTERY STATUS INDICATORS</b>	The Battery Status Indicators show the capacity of the Radical-7 Handheld and optional Docking Station batteries. The indicator flashes when less than 15 minutes of battery life is left and the battery needs to be recharged. The Docking Station Battery Status indicator is not shown when the optional Docking Station battery is not present.
⑭	<b>17 7</b>	<b>SpHb ALARM LIMITS DISPLAY</b>	The SpHb Alarm Limits Display shows the upper and lower alarm limits. When the measured value is outside of the alarm limits, the SpHb measurement display flashes and an alarm will sound.
⑮		<b>TOUCH KEY CONTROL BUTTONS</b>	Press a Touch Key Control Button to select the corresponding touch key icon. See Section 4, Touch Key Control Buttons and Icons for more details.
⑯		<b>BACKLIGHT BUTTON</b>	Press the Backlight Button to change the illumination level of the backlight. With the AC line power connected, five levels of illumination are available. In the Handheld mode, four levels of illumination are available. Use the lowest illumination for most efficient battery usage.
⑰		<b>ALARM SILENCE BUTTON</b>	Press the Alarm Silence Button to temporarily silence patient and low battery alarms. Press the Alarm Silence Button when the "Sensor Off" message is flashing (i.e. the sensor is removed from the patient) to acknowledge the end of monitoring. In this state, all further alarms are suspended until the Pulse CO-Oximeter starts measuring SpO <sub>2</sub> , SpCO, SpMet, SpHb and pulse rate again. <b>NOTE:</b> System failure alarms can be silenced by pressing the Power/Standby or Alarm Silence Button. If the Power/Standby Button does not silence the system fault alarm, press the Alarm Silence Button.
⑱		<b>SPEAKER</b>	The speaker indicates audio alarms. Care should be taken not to cover the speaker and muffle the audible alarm volume.
⑲		<b>PATIENT CABLE CONNECTOR</b>	Connect a patient cable or a direct cable sensor into the Handheld Radical-7 by plugging the cable into the Patient Cable Connector. Use only Masimo compatible sensors and cables with this Pulse CO-Oximeter. See Section 8, Sensors and Patient Cables, for more details.
⑳		<b>POWER/ON/OFF BUTTON</b>	Press the Power/On/Off Button to turn the instrument on. Press, hold the button for more than 2 seconds and then release the button to turn the instrument off.
㉑		<b>TOUCH KEY ICONS</b>	The Touch Key Icons indicate the software menu items that can be selected through the Touch Key Control Buttons. Pressing a Touch Key Control Button next to an icon selects the option.

\* For instruments that include SpMet, SpCO and SpHb parameters: the SpMet, SpCO, SpHb and SpOC parameters/measurements will be dimly lit in the display screen if a patient cable is not attached or a non-Rainbow sensor is being used.

**NOTE:** The Pulse CO-Oximeter display view will be different without the optional SpCO, SpMet and SpHb parameters/measurements.



## HANDHELD FRONT PANEL (CONTINUED)

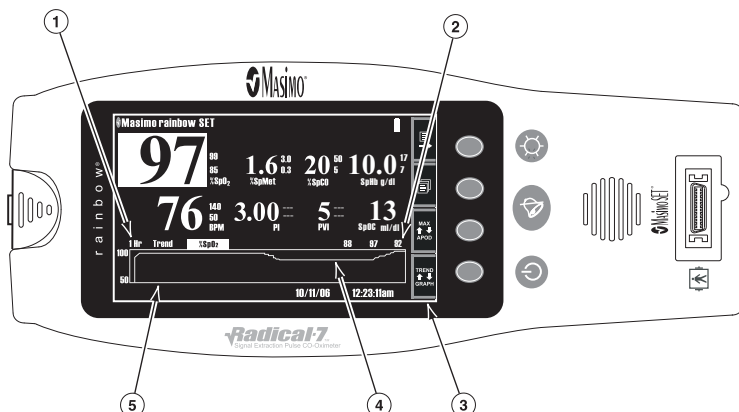
(22)	<b>13</b>	<b>SpOC* MEASUREMENT DISPLAY</b>	The measurement of total oxygen content is displayed in units of milliliter per deciliter.
(23)	<b>SENSOR 4 hrs</b>	<b>SENSOR TIME</b>	<p>Sensor Time displays the amount of time remaining (for SpHb Rainbow Reusable sensors) in the lower, right-hand corner of the screen. The Sensor Time is displayed in "X" Hrs" or "XX Min." As the sensor monitors the patient, the amount of time decreases to "0". Once the sensor time shows "0", the sensor must be replaced.</p> <p>The Sensor Time and the Time and Date Indicator show in the same location when the Time and Date Indicator is set to show on the screen. Subsequently, the Sensor Time replaces the Time and Date Indicator for 2 minutes at the following Sensor Times: 4 hours, 2 hours, 1 hour and 0 minutes. Refer to Section 4, <i>Sensor Time Remaining</i> for additional information. Once the Sensor Time reads 2 minutes, the Sensor Time will continue showing as it decreases to "0".</p>
	<b>10/11/06 12:23:11am</b>	<b>TIME AND DATE INDICATOR</b>	The Time and Date Indicator displays the current time and date. The time is displayed in 12 or 24 hour format. The date is displayed in dd/mm/yy or mm/dd/yy format. Select the date and time display formats in the Clock menu.
(24)	<b>5</b>	<b>PLETH VARIABILITY INDEX</b>	PVI is displayed as a percentage. The lower the number, the less variability there is in the PI over a respiratory cycle.
(25)		<b>SIGNAL IQ</b>	The Signal IQ shows the acquired signal quality and the timing of the pulse. A tall vertical line indicates a high quality signal, while a short vertical line indicates a low quality signal. The Signal IQ will be displayed as a single, pulsating bar in the Numbers mode.
(26)		<b>PULSE WAVEFORM DISPLAY</b>	The Pulse Waveform Display shows the acquired plethysmographic waveform. The plethysmographic waveform is scaled with signal strength. Signal strength is defined as the relation of arterial pulsatile signal to the non-pulsatile signal component.
(27)		<b>BRIGHTNESS LEVEL</b>	The Brightness level icon displays when utilizing the Backlight/Contrast button.
(28)	<b>3.00</b>	<b>PERFUSION INDEX</b>	The Perfusion Index indicates numerically the percentage of pulsatile signal to non-pulsatile signal (pulse strength).
(29)	<b>APOD</b>	<b>SENSITIVITY</b>	The sensitivity icon is shown on the Radical-7 display to indicate if the Radical-7 is set to operate in Normal, Maximum (MAX) or Adaptive Probe Off Detection (APOD) mode. When in Normal mode, this area will appear blank.
(30)	<b>140 50</b>	<b>PULSE RATE ALARM LIMITS DISPLAY</b>	The Pulse Rate Alarm Limits Display shows the upper and lower pulse rate alarm limits. When an alarm limit is exceeded, the pulse rate value and the violated limit flashes.
(31)	<b>FastSat</b>	<b>FASTSAT</b>	The FastSat® label is shown on the Radical-7 display whenever the Radical-7 is set to operate in the FastSat mode.
(32)	<b>76</b>	<b>PULSE RATE</b>	The Pulse Rate Measurement Display shows the patient's pulse rate in beats per minute. The upper and lower pulse rate alarm limits are also displayed next to the pulse rate measurement. The pulse rate is calculated and the display is updated at a frequency of once per second.

\* For instruments that include SpMet, SpCO and SpHb parameters: the SpMet, SpCO, SpHb and SpOC parameters/measurements will be dimly lit in the display screen if a patient cable is not attached or a non-Rainbow sensor is being used.

**NOTE:** The Pulse CO-Oximeter display view will be different without the optional SpCO, SpMet and SpHb parameters/measurements.

### MAIN SCREEN TREND GRAPH DISPLAY

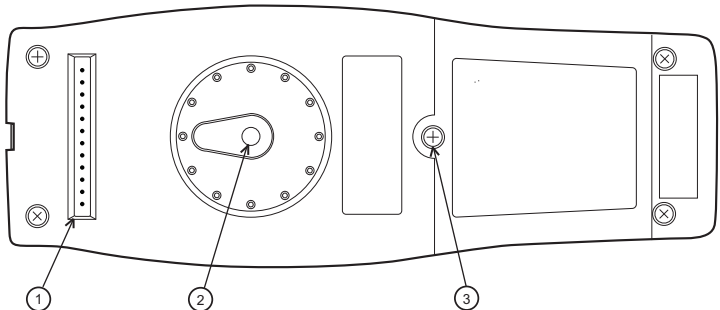
The Radical-7 Pulse CO-Oximeter provides a Trend Graph display function, which allows the user to quickly check the trend of each parameter/measurement. This is done by repeatedly pressing down on the Trend Graph control button to step through and select the desired parameter/measurement. Once the parameter/measurement is selected, the numeric value is highlighted and the selected parameter/measurement is displayed above the trend graph.






①	The first top line of the trend graph display shows the time scale of the trend graph followed by the selected parameter/measurement. The parameter/measurement's numeric value is highlighted.
②	The second top line of the trend graph display shows the minimum, maximum and average measurements of the selected parameter/measurement contained in the displayed data set (excluding zero measurements).
③	The Trend Graph control button initiates the trend graph display. Repeatedly pressing the button will step through each parameter/measurement, highlighting the numeric value and displaying the parameter/measurement above the trend graph.
④	The lines on the trend graph indicate the minimum and maximum values of the parameter/measurement.
⑤	The trend graph shows the desired parameters/measurements displayed versus time and the scale range.

## HANDHELD BACK PANEL

The Handheld back panel features the interconnection to the Docking Station, an accessory mount for the pole clamp accessory and access to the Handheld battery pack.



①		<b>DOCKING STATION CONNECTOR</b>	The Radical-7 Handheld interfaces with the Docking Station through this connector.
②		<b>POLE CLAMP ACCESSORY HOLDER</b>	The optional Pole Clamp accessory attaches to this holder. See the Directions for Use of the Pole Clamp accessory for attachment instructions.
③		<b>BATTERY PACK</b>	The Radical-7 Handheld is powered by a NiMH battery located in this compartment. For battery care and replacement please see Section 9, <i>Replacing the Batteries</i> .

## Radical-7 Pulse CO-Oximeter Standalone

When the Radical-7 Pulse CO-Oximeter Handheld is placed into the Docking Station, the Radical-7 Pulse CO-Oximeter becomes a full-featured standalone instrument. The Radical-7 Pulse CO-Oximeter Standalone acts as a battery charger for the Handheld instrument and has AC power connection capabilities. If the AC power from the wall outlet is temporarily interrupted, then the battery in the Handheld instrument will allow continuous operation. The Standalone can also interface to serial instruments, nurse call or analog output instruments, and multiparameter patient monitors through a SatShare cable.

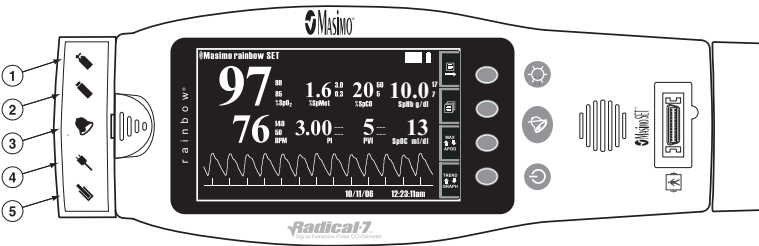
There are several models of Docking Stations available. The following table outlines which features are available for each model of Docking Station.

DOCKING STATION FEATURES	RDS-1	RDS-1B	RDS-2	RDS-3
AC Power Input	■	■	■	■
SatShare Interface	■	■		
Serial RS-232 Interface	■	■		■
Nurse Call/Analog Output Interface	■	■		■
10-hour Extended Battery		■		
Automatic Display Rotation Support (Gravity Detector)	■	■		■
Docking Station Battery Charging Indicator		■		
Handheld Battery Charging Indicator	■	■	■	■
Visual Alarm Indicator	■	■		■
AC Power Indicator	■	■	■	■
Docking Indicator	■	■		■
Handheld Battery Deep Discharge Support	■	■		■
Docking Station Battery Deep Discharge Support	■	■		■

The RDS-1 and RDS-3 are optionally available with Patient SafetyNet and RadNet capability. (Refer to Section 3, *Patient SafetyNet/RadNet Setup* for details)

## STANDALONE FRONT PANEL

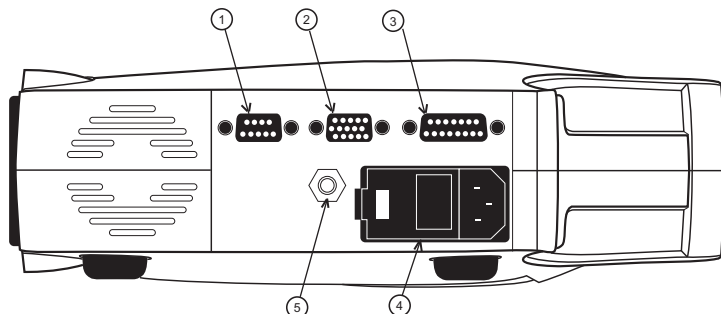
The following figure and corresponding text review the features of the Radical-7 Standalone instrument.



①		<b>DOCKING STATION BATTERY CHARGING INDICATOR</b>	The Docking Station Battery Charging Indicator is illuminated when the Docking Station battery is charging. The indicator blinks just prior to charging. The Charging Indicator does not illuminate when the battery is fully charged or when the battery is not present.
②		<b>HANDHELD BATTERY CHARGING INDICATOR</b>	The Handheld Battery Charging Indicator is illuminated when the Handheld battery is charging. The indicator blinks just prior to charging. The Charging Indicator does not illuminate when the battery is fully charged or when the battery is not present.
③		<b>VISUAL ALARM INDICATOR</b>	The Visual Alarm Indicator is illuminated when an alarm condition is active and the Alarm Status Indicator is shown.
④		<b>AC POWER INDICATOR</b>	The AC Power Indicator is illuminated when the Radical-7 Docking Station is plugged into AC line power.
⑤		<b>DOCKING INDICATOR</b>	The Docking Indicator is illuminated when the Handheld instrument is turned on and is properly interfaced to a Docking Station.

**NOTE:** When the Radical-7 Pulse CO-Oximeter Standalone is turned on, all indicator LEDs initially turn on and off at start up.

## STANDALONE BACK PANEL






















①	<b>SERIAL OUTPUT CONNECTOR</b>	Use the Serial Output Connector with a ferrite bead installed to connect a serial instrument, including a serial printer, a monitoring system or PC to the Radical-7 Pulse CO-Oximeter. The data is provided in standard RS-232C format. See Section 7, <i>Serial Interface Specifications</i> . All external instrument connections to the Serial Output Connector must be IEC-60950 compliant.
②	<b>ANALOG OUTPUT / NURSE CALL CONNECTOR</b>	Use the Analog Output Connector with a ferrite bead installed to interface with an analog output instrument, such as a chart recorder or nurse call system. All external instrument connections to the Analog Output / Nurse Call Connector must be IEC-60950 compliant.
③	<b>SATSHARE CABLE CONNECTOR</b>	Use the SatShare Cable Connector to connect a SatShare cable to the SpO <sub>2</sub> input connector of a multiparameter patient monitor. All external instrument connections to the SatShare Cable Connector must be IEC-60601-1-1 compliant. SatShare cables are available to interface with most major multiparameter patient monitors. Check the label on the SatShare cable and the SatShare Directions for Use to ensure that the correct cable is used for each type of patient monitor. Refer to Section 10, <i>Accessories</i> of this manual or the Masimo web site at <a href="http://www.masimo.com">www.masimo.com</a> for the latest SatShare cables and validated instruments.
④	<b>POWER ENTRY MODULE</b>	The power entry module contains the input connector for AC power and two fuses. The AC input provides power to the system from the AC line. Always connect the Pulse CO-Oximeter to the mains power for continuous operation and/or battery recharging.  <b>NOTE:</b> Use the power cord as the means to disconnect the instrument from the mains power supply.
⑤	<b>EQUIPOTENTIAL GROUND CONNECTOR</b>	Use the Equipotential Ground Connector for grounding.

## SYMBOLS

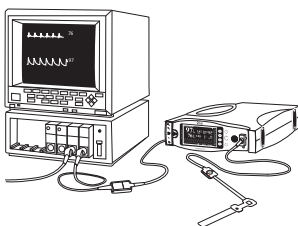
The following symbols are found on the Radical-7 Pulse CO-Oximeter, Docking Station or packaging and are defined below:

**NOTE:** Some of the interfaces and symbols are not available on all versions of the Docking Station.

SYMBOLS	DEFINITION
 RS-232	RS-232
	SatShare Interface
	Equipotential Ground Terminal
	See Instructions for Use
	Fuse Replacement
	Analog Out Interface
	Nurse Call Interface
	WEEE Compliant
	Mark of Conformity to European Medical Instrument Directive 93/42/EEC
Rx ONLY	Federal law restricts this instrument to sale by or on the order of a physician (USA audiences only)
	Underwriter's Laboratories Inc. certification
	Storage humidity range: 5% to 95%
	Storage temperature range: +70°C to -40°C Storage altitude range: +1600hPa to +500hPa
	Keep dry
	Fragile/breakable, handle with care
	Year of Manufacture
IPX1	Protection against liquid drops falling vertically
	Defibrillation Proof Type BF
	EU authorized representative
	CAUTION
	Manufacturer

## Radical-7 Monitor Interface

In addition to being a full-featured Handheld and Standalone Pulse CO-Oximeter, the Radical-7 Pulse CO-Oximeter's unique SatShare interface links the Radical-7 Pulse CO-Oximeter to most existing multiparameter patient monitors through the pulse oximetry patient cable or SpO<sub>2</sub> input connector.



- Upgrades any approved and validated monitor to Masimo SET performance by using the calculated SpO<sub>2</sub> and pulse rate determined by Radical-7 to simulate an ideal waveform, which is sent to the validated multiparameter patient monitor.
- Connects into the SpO<sub>2</sub> patient cable or SpO<sub>2</sub> input connector of the multiparameter patient monitor.

Refer to Section 3, *SatShare Setup* and Section 4, *SatShare Operation* for additional details.

### CAUTIONS:

- THE WAVEFORM DISPLAYED ON THE MULTIPARAMETER PATIENT MONITOR IS A SIMULATED SIGNAL (NON-NORMALIZED). REFER TO THE RADICAL-7 PULSE CO-OXIMETER DISPLAY FOR PATIENT WAVEFORM.
- IF DISPLAYING THE SIMULATED WAVEFORM IS NOT DESIRABLE, IT IS RECOMMENDED TO TURN OFF THE PLETHYSMOGRAPHIC WAVEFORM DISPLAY ON THE MULTIPARAMETER MONITOR.
- ONLY USE A SATSHARE CABLE THAT HAS A FERRITE BEAD INSTALLED.
- ONLY SpO<sub>2</sub> AND PULSE RATE CAN BE DISPLAYED ON THE MULTIPARAMETER MONITOR WITH SATSHARE.



## Introduction

Before the Radical-7 Pulse CO-Oximeter can be used in a clinical setting, it needs to be inspected, properly setup and the batteries need to be fully charged.

## Unpacking and Inspection

Remove the instrument from the shipping carton and examine it for signs of shipping damage. Check all materials against the packing list. Save all packing materials, invoice and bill of lading. These may be required to process a claim with the carrier.

If anything is missing or damaged, contact the Technical Service Department. The contact address and phone numbers are listed in Section 9, *Service and Repair*.

## Preparation for Monitoring

The following sections of the manual describe the preparation, set-up and initial installation of the Radical-7 Pulse CO-Oximeter.

### RADICAL-7 DOCKING STATION POWER REQUIREMENTS

Always use a hospital grade, AC power cable to connect the Radical-7 Pulse CO-Oximeter to an AC power source. Do not connect the Radical-7 Docking Station to an AC outlet controlled by a switch because the power to the instrument may be inadvertently switched off.

Verify the AC power voltage and line frequency before use. Verify that the power source can provide adequate power rating as indicated on the rear panel of the Radical-7 Docking Station.

The Radical-7 Pulse CO-Oximeter is designed to operate on 100 to 240VAC, 47-63 Hz. The instrument is rated at 55 VA max.

Connect a hospital grade power cable to the power entry module of the Radical-7 instrument (IEC-320 connector type at the instrument). Connect the power cable to an AC power source. Ensure that the instrument is adequately powered by verifying that the AC power indicator on the Docking Station is illuminated.

#### CAUTION:

- DO NOT UNDER ANY CIRCUMSTANCES REMOVE THE GROUNDING CONDUCTOR FROM THE POWER PLUG.
- DO NOT USE EXTENSION CORDS OR ADAPTERS OF ANY TYPE. THE POWER CORD AND PLUG MUST BE INTACT AND UNDAMAGED.
- USE THE POWER CORD AS THE MEANS TO DISCONNECT THE INSTRUMENT FROM THE AC POWER AT THE WALL OUTLET.
- IF THERE IS ANY DOUBT ABOUT THE INTEGRITY OF THE PROTECTIVE EARTH CONDUCTOR ARRANGEMENT, OPERATE THE PULSE CO-OXIMETER ON INTERNAL BATTERY POWER UNTIL THE AC POWER SUPPLY PROTECTIVE CONDUCTOR IS FULLY FUNCTIONAL.
- TO ENSURE PATIENT ELECTRICAL ISOLATION, CONNECT ONLY TO OTHER EQUIPMENT WITH ELECTRICALLY ISOLATED CIRCUITS.
- DO NOT CONNECT TO AN ELECTRICAL OUTLET CONTROLLED BY A WALL SWITCH OR DIMMER.

### INITIAL BATTERY CHARGING

Before use, the Radical-7 Pulse CO-Oximeter Handheld battery and the optional Docking Station battery need to be fully charged.

To charge the batteries:

1. Attach the Handheld instrument to the Docking Station.
2. Plug in the AC power cord to power entry module. Make sure it is securely plugged in.
3. Plug the AC power cord into an AC power source.
4. Verify that the batteries are charging.

The battery charging LED indicators on the Docking Station flash prior to charging and remain illuminated while the batteries are charging.

Refer to Section 9, *Battery Operation and Maintenance*, for proper battery charging.

### INITIAL INSTALLATION

Place the Docking Station on a stable hard flat surface near the patient. Always place the Radical-7 Pulse CO-Oximeter instrument on a dry surface. Maintain a minimum of 3 cm (1 inch) free space around the Radical-7 Pulse CO-Oximeter Standalone instrument. Make sure that the Radical-7 speaker is not covered to avoid a muffled alarm sound.

The Radical-7 Pulse CO-Oximeter Handheld, Docking Station or Standalone should not be operated outside the following environmental conditions:

OPERATING ENVIRONMENTAL CONDITIONS	
TEMPERATURE	+5°C to +40°C, +41°F to +104°F
HUMIDITY	5% to 95%, non-condensing
OPERATING ALTITUDE	1060 mbar to 500 mbar pressure -1000 ft to 18,000 ft (-304 m to 5,486 m)

Configure the instrument for your regional power line frequency (50 or 60 hz) if needed. Default is 60 hz (standard for the United States). See Section 4, *Operation, Config*.

**CAUTION:** THE INSTRUMENT MUST BE CONFIGURED TO MATCH YOUR LOCAL POWER LINE FREQUENCY TO ALLOW FOR THE CANCELLATION OF NOISE INTRODUCED BY FLUORESCENT LIGHTS AND OTHER SOURCES.

## Monitor Setup

The Radical-7 Pulse CO-Oximeter maintains three types of default values, which the instrument will automatically revert to after a power cycle:

- Factory – these options are restored to factory values.
- Custom – these settings can be changed by the user and retained through the power cycle.
- Adult / Neo – these settings can be selected to revert to factory or hospital-defined values (for Adult or Neonatal) after a power cycle.

### FACTORY DEFAULT SETTINGS

The following outlines the Radical-7 Pulse CO-Oximeter option settings that can be changed by the user but will revert back to after a power cycle.

OPTION	DEFAULT SETTINGS
<b>LCD SCREEN ILLUMINATION</b>	
AC Power	Set to maximum, level 5
Battery Power	Set to minimum, level 1
<b>SENSITIVITY</b>	Set to APOD mode

### CUSTOM (USER) DEFINED SETTINGS

This mode is indicated by "Mode Custom" on the Alarms menu.

The following table outlines the options that may be changed by the user and that the Radical-7 Pulse CO-Oximeter will remember after a power cycle. The default settings listed below are those set at the factory and to which the instrument will revert if the user chooses to recall the factory settings. (see Section 4, *Display*)

OPTION	FACTORY DEFAULT SETTING	CONFIGURABLE SETTING
<b>DISPLAY VIEW</b>	Set to Pleth + SigIQ	Pleth + SigIQ, Pleth Only, PVI Pleth + SigIQ, PVI Pleth, Numbers
<b>AVERAGING TIME</b>	Set to 8	2, 4, 8, 10, 12, 14, or 16 seconds
<b>FASTSAT</b>	Set to No	Yes/No
<b>HOME USE</b>	Set to No	Yes/No
<b>INTERFACE ALARMS SpO<sub>2</sub>/PULSE RATE</b>	Set to Yes	Yes/No
<b>SATSHARE NUMBERS</b>	Set to Yes	Yes/No
<b>POWER SAVE</b>	Set to No	Yes/No
<b>DATE FORMAT</b>	Set to mm/dd/yy	mm/dd/yy and dd/mm/yy
<b>TIME FORMAT</b>	Set to 12 hr	12 or 24 hour
<b>LANGUAGE</b>	Set to English	See Section 4, <i>Display</i> for all settings
<b>ANALOG OUTPUT</b>	Set to Analog 1: SpO <sub>2</sub> 0-100%	See Section 4, <i>Display</i> for all settings
	Set to Analog 2: Pulse Rate	
<b>SERIAL OUTPUT PORT MODE</b>	Set to ASCII 1	ASCII 1, ASCII 2, Binary, Philips Vuelink, Spacelabs Flexport
<b>PULSE BEEP VOLUME</b>	Set to Level 4	Level 1 to 7
<b>ALARM VOLUME</b>	Set to Level 3	Level 1 to 4

## CUSTOM (USER) DEFINED SETTINGS (CONTINUED)

OPTION	FACTORY DEFAULT SETTING	CONFIGURABLE SETTING
TREND DISPLAY PARAMETERS/ MEASUREMENTS	Set to %SpO <sub>2</sub> + BPM	See Section 4, <i>Display</i> for all settings.
TREND PERIOD	Set to 1 Hr	See Section 4, <i>Trend Setup</i> for all settings.
SpHb TREND	Set to Yes	Yes/No
LOW SpO <sub>2</sub> ALARM LIMIT	Set to 0	(Refer to Section 4, <i>Display</i> for details on this user adjustable feature)
SpHb AVERAGING	Set to Medium	Short, Medium, Long
SpMet HIGH/LOW ALARM LIMIT	Set to High: 3.0/Low: ---	See Section 4, <i>Alarms</i> for all settings.
SpCO HIGH/LOW ALARM LIMIT	Set to High: 10/Low: ---	
SpHb HIGH/LOW ALARM LIMIT	Set to High: 17.0/Low: 7.0	
PI HIGH/LOW ALARM LIMIT	Set to High: ---/Low: ---	
PVI HIGH/LOW ALARM LIMIT	Set to High: ---/Low: ---	
SMART TONE	Set to No	Yes/No
PI AVERAGING	Set to Short	Short, Long
PVI AVERAGING	Set to Long	Short, Long
DISPLAY MEASUREMENT	SpOC	SpOC, None
SpHb PRECISION	Set to 0.1	0, 0.1, 0.5
SpHb CAL	Arterial	Arterial, Venous

## ADULT/NEO SETTINGS (PRE-DEFINED)

The following table outlines settings that may be defined by the hospital. If enabled (via a password protected screen, see Section 4, *Password Operation*), these settings will return to pre-defined values after a power cycle. This mode is indicated by "Mode Adult" or "Mode Neo" on the Alarms menu. See Section 4, *Operation* for details on enabling and setting these parameters/measurements.

OPTION	CUSTOM SETTING (DEFAULT)	ADULT/NEO SETTING (PRE-DEFINED)
SPO <sub>2</sub> HIGH/LOW ALARM LIMIT	Set to High: ---/Low: 90	Same settings
PULSE RATE HIGH/LOW ALARM LIMIT	Set to High: 140/Low: 50 BPM	
SpMet HIGH/LOW ALARM LIMIT	Set to High: 3.0/Low: ---	
SpCO HIGH/LOW ALARM LIMIT	Set to High: 10/Low: ---	
SpHb HIGH/LOW ALARM LIMIT	Set to High: 17.0/Low: 7.0	
PI HIGH/LOW ALARM LIMIT	Set to High: ---/Low: ---	
PVI HIGH/LOW ALARM LIMIT	Set to High: ---/Low: ---	
ALARM SILENCE	Set to 120 seconds	
ALARM VOLUME	Set to 3	
ALARM DELAY	Set to 5	
SpHb CAL	Set to Arterial	

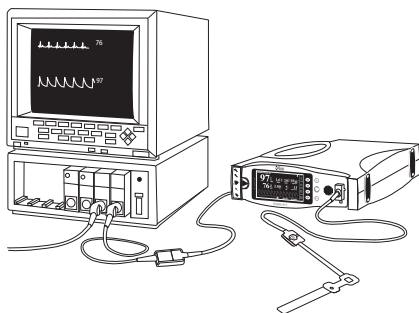
## SatShare Setup

The Radical-7 Pulse CO-Oximeter has been proven to be accurate during patient motion and low perfusion conditions. Saturation and pulse rate values from the Radical-7 Pulse CO-Oximeter may be displayed on a multiparameter monitor through the SatShare feature.

The SatShare feature provides an ideal, simulated waveform corresponding to the measured saturation and pulse rate values determined by the Masimo SET technology. This waveform may be used to display these values on multiparameter monitors through the multiparameter oximetry sensor or input connector.

It is recommended that the Radical-7 Pulse CO-Oximeter is positioned close to the multiparameter monitor with the Radical-7 Pulse CO-Oximeter screen visibly displaying the plethysmographic waveform and the saturation and pulse rate measurements.

**CAUTION:** SIMULTANEOUS USE OF SATSHARE AND SERIAL PORT IS NOT SUPPORTED.



### SATSHARE SETUP

1. Select the SatShare cable that is appropriate for the multiparameter monitor that is being connected. Check the Masimo web site at [www.masimo.com](http://www.masimo.com) for the latest list of available SatShare cables and validated instruments.
2. Connect the labeled end of the cable to the SatShare Cable Connector port on the back of the Docking Station. Tighten the connector screws for a secure connection.
3. Connect the other end of the SatShare cable either to the sensor connector of the multiparameter monitor's SpO<sub>2</sub> cable or directly to the SpO<sub>2</sub> connector on the monitor.
4. Verify that the Radical-7 Pulse CO-Oximeter recognizes the correct cable. The name of the SatShare cable will be displayed on the LCD screen when the SatShare mode is functional.
5. Set the multiparameter monitor's high and low saturation and pulse rate alarm limits as appropriate.
6. Set the multiparameter monitor's averaging time to the lowest setting (i.e. fastest response). The Radical-7 Pulse CO-Oximeter's ideal waveform necessitates the need for additional averaging by the monitor. If the multiparameter monitor's averaging time is not changed, the time to display physiological changes in saturation on the monitor will be increased with SatShare. However, the delay can be minimized by reducing the multiparameter monitor's averaging time.

### SATSHARE SETUP (CONTINUED)

7. While in the SatShare mode, if there are any significant discrepancies between the readings from the Radical-7 Pulse CO-Oximeter and those on the monitor displaying the values obtained from SatShare, the values reported by the Radical-7 Pulse CO-Oximeter are to be considered the correct values.
8. To use the Radical-7 Pulse CO-Oximeter with SatShare while it is not connected to AC power, set the Power Save parameter in the General menu to "No" and refer to Section 4, *Operation*. Please note that if the Radical-7 Pulse CO-Oximeter is used in this mode, the length of time the Radical-7 Pulse CO-Oximeter can operate on battery power will be significantly diminished.
9. Set the SatShare Numbers and the Interface Alarms SpO<sub>2</sub>/pulse rate parameters in the General menu according to customer preference.

When Rainbow parameters (SpCO, SpMet, SpHb, etc.) are configured, Interface Alarms "SpO<sub>2</sub>/BPM" can be set to "Yes" or "No". The "Yes" setting allows SpO<sub>2</sub> and pulse rate audible alarms at both the Radical-7 and the interfaced system. The "No" setting mutes the SpO<sub>2</sub> and pulse rate audible alarms at the Radical-7 while allowing SpO<sub>2</sub> and pulse rate audible alarm alerts at the interfaced system. The "No" setting prevents both systems (Radical-7 and interfaced system) from producing audible alarms at the same time. See section 4: General.

**NOTE:** The Radical-7 reverts to Interface Alarm "SpO<sub>2</sub>/BPM" "Yes" during power interruptions or when the SatShare connection is lost or the instrument becomes separated from the docking station. This ensures that the Radical-7 provides audible alarms for SpO<sub>2</sub> and pulse rate when the connection to the interfaced system becomes compromised.

10. If displaying the simulated waveform is not desirable, it is recommended to turn off the plethysmographic waveform display of the multiparameter patient monitor.
  - SATSHARE SIGNALS ARE IDEAL SIMULATED WAVEFORMS CORRESPONDING TO THE CALCULATED SATURATION AND PULSE RATE VALUES AND DO NOT CONTAIN ALL OF THE INFORMATION CONTAINED IN PHYSIOLOGICAL WAVEFORMS. THE MULTIPARAMETER PATIENT MONITOR TRANSLATES THESE SIGNALS INTO SATURATION AND PULSE RATE VALUES.
  - DURING SATSHARE OPERATION, THE AUDIBLE ALARMS MAY BE MUTED ON THE RADICAL-7 PULSE CO-OXIMETER. WHEN THE AUDIBLE ALARM IS MUTED (INDICATED BY THE BELL WITH A SLASH THROUGH IT) ON THE RADICAL-7 PULSE CO-OXIMETER, USE THE MULTIPARAMETER MONITOR FOR AUDIBLE ALARM INDICATION.
  - DURING SATSHARE OPERATION DO NOT USE THE PLETHYSMOGRAPHIC WAVEFORM DISPLAY ON THE MULTIPARAMETER MONITOR FOR DIAGNOSTIC PURPOSES. INSTEAD, USE THE PLETHYSMOGRAPHIC WAVEFORM DISPLAYED ON THE RADICAL-7 PULSE CO-OXIMETER SCREEN.
  - TO AVOID EXCESSIVE BATTERY DISCHARGING, DO NOT CONNECT ANY EQUIPMENT TO THE SATSHARE CONNECTOR UNLESS THE RADICAL-7 PULSE CO-OXIMETER IS CONNECTED TO THE AC MAINS POWER SUPPLY.
  - ONLY USE A SATSHARE CABLE THAT HAS A FERRITE BEAD INSTALLED.
  - ONLY SpO<sub>2</sub> AND PULSE RATE CAN BE DISPLAYED ON THE MULTIPARAMETER MONITOR WITH SATSHARE.

- THE RADICAL-7 REVERTS TO INTERFACE ALARM SpO<sub>2</sub>/BPM “Yes” DURING POWER INTERRUPTIONS OR WHEN THE SATSHARE CONNECTION IS LOST OR THE Instrument BECOMES SEPARATED FROM THE DOCKING STATION. THIS ENSURES THAT THE RADICAL-7 PROVIDES AUDIBLE ALARMS FOR SpO<sub>2</sub> AND PULSE RATE WHEN THE CONNECTION TO THE INTERFACED SYSTEM BECOMES COMPROMISED.

## Philips VueLink Setup

### CAUTIONS:

- SIMULTANEOUS USE OF SATSHARE AND SERIAL PORT IS NOT SUPPORTED.
- IF THE RADICAL DOCKING STATION IS COMPATIBLE WITH PATIENT SAFETYNET OR RADNET™, VUELINK IS NOT SUPPORTED.
- ONLY SpO<sub>2</sub> AND PULSE RATE CAN BE DISPLAYED ON THE MULTIPARAMETER MONITOR WITH VUELINK.

**WARNING:** EXTERNAL INSTRUMENT CONNECTIONS TO THE SATSHARE PORT MUST BE IEC-60601-1-1 COMPLIANT.

1. Select the Philips VueLink selection from the Output menu on the Radical-7 Pulse CO-Oximeter. Refer to Section 4, *Output*.
2. Connect one end of the VueLink cable to the Serial Output connector on the back of the Docking Station.
3. Connect the other end of the VueLink cable to the VueLink module and insert the module into the Philips monitor rack.
4. The SpO<sub>2</sub> and pulse rate values will automatically appear on the Philips monitor.
5. In order for the plethysmographic waveform to be displayed on the Philips monitor and for the Philips monitor to indicate the alarm conditions measured by the Pulse CO-Oximeter, the user must configure the Philips monitor. Refer to the Philips Operator's Manual for complete instructions.
6. The Radical-7 can be set up to audibly indicate all patient alarms while communicating with the Philips VueLink module. Use the Interface Alarms setting in the General menu to enable and disable audible alarms on the Radical-7.

## Spacelabs Universal Flexport Setup

### CAUTIONS:

- SIMULTANEOUS USE OF SATSHARE AND SERIAL PORT IS NOT SUPPORTED.
  - ONLY SpO<sub>2</sub> AND PULSE RATE CAN BE DISPLAYED ON THE MULTIPARAMETER MONITOR WITH FLEXPORT.
1. Select the Spacelabs Flexport selection from the Output menu on the Radical-7.
  2. Connect one end of the Spacelabs Flexport cable to the Serial Output connector on the back of the Docking Station.
  3. Connect the other end of the Spacelabs Flexport cable to the Spacelabs Universal Flexport connector.
  4. The SpO<sub>2</sub> and pulse rate values will automatically appear on the Spacelabs screen.

5. In order for the plethysmographic waveform to be displayed on the Spacelabs screen and for the Spacelabs monitor to indicate the alarm conditions measured by the Pulse CO-Oximeter, the user must configure the Spacelabs monitor. Refer to the Spacelabs monitor Operator's Manual for complete instructions.
6. The Radical-7 Pulse CO-Oximeter can be set up to audibly indicate all patient alarms while communicating with the Spacelabs Flexport module. Use the Interface Alarms setting in the General menu to enable and disable audible alarms on the Radical-7 Pulse CO-Oximeter.

## Patient SafetyNet/RadNet Setup

### CAUTIONS:

- SIMULTANEOUS USE OF SATSHARE AND SERIAL PORT IS NOT SUPPORTED.
- ONLY SpO<sub>2</sub> AND PULSE RATE CAN BE DISPLAYED ON THE MULTIPARAMETER MONITOR WITH PATIENT SAFETYNET AND RADNET.

**NOTE:** Confirm that the Radical Docking Station is Patient SafetyNet and RadNet Ready before proceeding. This is done by pressing the **Menu** button then selecting **About**. Confirm that the "D-Station" software displays (RadNet) next to the version number.

1. Select the ASCII 2 selection from the Serial options on the Output Menu on the Radical-7 Pulse CO-Oximeter.
2. Connect one end of the serial cable to the Serial Output connector on the back of the Docking Station.
3. Connect the other end of the serial cable to the Patient SafetyNet wireless radio or RadNet Interface Module connector.
4. Turn the Patient SafetyNet wireless radio or RadNet Interface Module on.
5. With a properly configured, the Patient SafetyNet wireless radio or RadNet Interface Module, the Radical-7 will automatically display the plethysmographic and SIQ waveforms as well as the installed numeric parameters on the Patient SafetyNet Detail View and on the screen at the RadNet Central Station.

**CAUTION:** ENSURE THAT THE RADICAL-7 PULSE CO-OXIMETER HANDHELD REMAINS IN THE RADNET READY DOCKING STATION WHEN CONNECTED TO THE MONITORING SYSTEM. REMOVING THE RADICAL-7 PULSE CO-OXIMETER HANDHELD FROM THE RADNET READY DOCKING STATION WILL CAUSE LOSS OF COMMUNICATION TO THE PATIENT SAFETYNET OR RADNET CENTRAL MONITORING STATION.

**CAUTION:** WHEN THE RADICAL-7 IS PLACED IN **ALL MUTE**, THE PATIENT ALARMS WILL NOT AUDIBLY SOUND ON THE RADICAL-7, THE PATIENT SAFETYNET OR THE RADNET CENTRAL STATION. THE RADNET CENTRAL STATION WILL DISPLAY A VISUAL ALARM.



## Introduction

To operate the Radical-7 Pulse CO-Oximeter effectively, the instrument must be set up properly and the operator must:

- Know how the Pulse CO-Oximeter derives its readings (see Section 1, *Pulse CO-Oximetry*).
- Be familiar with its controls, components and operation.
- Understand its status and alarm messages (see Section 5, *Alarm Identification, System Messages* and Section 6, *Troubleshooting*).

## Basic Operation

### GENERAL SETUP AND USE

1. Inspect the Pulse CO-Oximeter case for damage.
2. Connect a patient cable or a direct cable sensor to the Patient Cable Connector of the Radical-7 Pulse CO-Oximeter. Make sure it is a firm connection and the cable is not twisted, sliced or frayed.
3. If utilizing the Standalone setup, ensure that the power cord is plugged into the Power Cable Connector of the Docking Station and into the AC power.
4. Select a sensor that is compatible with the Pulse CO-Oximeter before connecting it to the patient cable or instrument. See section 8, *Sensors and Patient Cables*. If using a single patient adhesive or disposable sensor, check that the emitter (red light) and the detector are properly aligned. Remove any substances that may interfere with the transmission of light between the sensor's light source and detector.
5. Attach the sensor to the patient. Refer to the Directions for Use of the sensor.
6. Connect the sensor to the instrument (or patient cable) with the logos lining up; make sure it is a firm connection.
7. Press the Power/Standby button to turn the Pulse CO-Oximeter on.
8. Make sure the display window is free of alarm and system failure messages (see Section 5, *Alarms and Messages*).
9. On the display, verify:
  - The high and low alarm limits for SpO<sub>2</sub>, SpMet, SpCO, SpHb, PI, PVI, and pulse rate.
  - The readings for SpO<sub>2</sub>, SpMet, SpCO, SpHb, SpOC, PI, PVI, and pulse rate.
  - The remaining duration for the sensor, if applicable.

**NOTE:** “- -” initially shows in the numeric display fields for all the parameters/measurements when the Radical-7 is turned on. As the system starts monitoring, the numeric display fields update (refresh). The numeric display fields for the parameters/measurements begin to show numbers during the refresh cycles even though the numbers have not stabilized; during this period, the measurement label will flash to indicate that the measurement value is being processed. When the flashing stops, the number has stabilized (less than 15 seconds for SpO<sub>2</sub>, PI and pulse rate; up to 25 seconds for SpCO and SpMet. In the case of SpHb, the numeric value will be displayed upon initial stabilization of the number (up to 90 seconds), and the parameter label will continue to flash for an additional processing period to reach optimal confidence (60 seconds). In the case of PVI, the numeric value will be displayed upon initial stabilization of the number (up to 120 seconds), and the parameter label will continue to flash for an additional processing period to reach optimal confidence (60 seconds).

## GENERAL SETUP AND USE (CONTINUED)

10. Verify that the patient alarms are functional by setting the high and low SpO<sub>2</sub>, SpMet, SpCO, SpHb, PI, PVI, and pulse rate alarm limits beyond the patient readings.
  - An alarm tone sounds.
  - The violated alarm limit and reading flash on the display.
  - The red alarm indicator flashes on the Docking Station (standalone operation).
11. Verify the sensor alarms are functional by removing the sensor from the sensor site.
  - "Sensor Off" appears in the message area of the graphic display.
  - The alarm tone sounds.
  - The alarm indicator flashes.
  - Disconnect the sensor from the patient cable or instrument.
  - Confirm that "Sensor Off" appears in the message area of the graphic display.
12. Verify alarm silence operation.
  - Create an alarm condition by lowering the SpO<sub>2</sub> or pulse rate high alarm limits beyond the patient readings.
  - Press the Alarm Silence button.
  - The alarm tone ceases for the displayed amount of time.
  - Perform the above steps for the SpCO and SpMet alarm limits.
13. To begin patient monitoring:
  - Adjust the alarm limits.
  - Adjust the alarm volumes.
  - Adjust the pulse beep volume.
14. Verify the sensor is on correctly and that the measured data is appropriate, see Section 4, *Successful Monitoring*.
15. Monitor the patient.
16. After monitoring is complete, remove the sensor from the patient and store or dispose of the sensor according to governing rules. See the Directions for Use of the sensor.
17. Press and hold the Power/Standby Button for 2 seconds to turn the instrument off.

## Successful Monitoring

The following general points will aid in ensuring Pulse CO-Oximetry monitoring success.

- Place the sensor on a site that has sufficient perfusion and provides proper alignment of the LEDs and detector.
- Place the sensor on a site that has unrestricted blood flow.
- Do not secure a sensor with tape.
- Do not select a site near potential electrical interference (electrosurgical unit, for example).
- Read the sensor Directions for Use for proper sensor application.

### NUMERIC DISPLAY - SpO<sub>2</sub>

Stability of the SpO<sub>2</sub> readings may be a good indicator of signal validity. Although stability is a relative term, experience will provide a good feeling for changes that are artifactual or physiological and the speed, timing, and behavior of each. The stability of the readings over time is affected by the averaging mode being used. The longer the averaging time, the more stable the readings tend to become. This is due to a dampened response as the signal is averaged over a longer period of time than during shorter averaging times. However, longer

averaging times delay the response of the oximeter and reduce the measured variations of SpO<sub>2</sub> and pulse rate.

## MASIMO SENSORS

Before use, carefully read the Masimo sensor Directions for Use.

**Use only Masimo sensors for pulse oximetry or pulse CO-Oximetry measurements.**

Tissue damage can be caused by incorrect application or use of a sensor, for example by wrapping the sensor too tightly. Inspect the sensor site as directed in the sensor Directions for Use to ensure skin integrity and correct positioning and adhesion of the sensor.

**NOTE:** When a Masimo Rainbow Sensor is properly connected to the patient, the instrument normally goes through a 20-30 second sensor calibration/pulse search routine and then displays numeric values for SpO<sub>2</sub>, SpMet, SpCO, SpHb, SpOC, pulse rate, Perfusion Index (PI) and Pleth Variability (PVI). It also provides graphical displays for plethysmographic waveform, Signal Identification and Quality Indicator (Signal IQ®). However, if the sensor calibration/pulse search routine is unsuccessful for Rainbow parameters/measurements, the instrument automatically switches to a "SpO<sub>2</sub> Only Mode" to provide SpO<sub>2</sub>, PR, PI and PVI parameters/measurements for the user.

If a Masimo Rainbow Direct Connect Reusable Sensor is being used and "SpO<sub>2</sub> Only Mode" appears on the display screen, perform one of the following steps to reset the instrument:

- Remove the sensor from patient (recommended).
- Remove the cable connector from instrument.
- Turn the power Off and On at the instrument.

If a Masimo Rainbow Adhesive Sensor is being used and "SpO<sub>2</sub> Only Mode" appears on the display screen, perform one of the following steps to reset the instrument:

- Disconnect sensor cable connector from the patient cable connector (recommended).
- Remove patient cable connector from instrument.
- Turn the power Off and On at the instrument.
- Remove the sensor from the patient.

To obtain successful monitoring, refer to Section 4, Successful Monitoring.

## CAUTIONS

- DO NOT USE DAMAGED SENSORS. DO NOT USE A SENSOR WITH EXPOSED OPTICAL OR ELECTRICAL COMPONENTS. DO NOT IMMERSE THE SENSOR IN WATER, SOLVENTS, OR CLEANING SOLUTIONS (THE SENSORS AND CONNECTORS ARE NOT WATERPROOF). DO NOT STERILIZE BY IRRADIATION, STEAM, AUTOCLAVE OR ETHYLENE OXIDE UNLESS OTHERWISE INDICATED IN THE SENSOR DIRECTIONS FOR USE. SEE THE CLEANING INSTRUCTIONS IN THE DIRECTIONS FOR USE FOR ALL MASIMO REUSABLE SENSORS.
- DO NOT USE DAMAGED PATIENT CABLES. DO NOT IMMERSE THE PATIENT CABLES IN WATER, SOLVENTS, OR CLEANING SOLUTIONS (THE PATIENT CABLE CONNECTORS ARE NOT WATERPROOF). DO NOT STERILIZE BY IRRADIATION, STEAM, AUTOCLAVE OR ETHYLENE OXIDE.

## SENSOR TIME REMAINING

The Radical-7 displays the amount of time remaining for SpHb Rainbow Reusable sensors (refer to Section 8, *Rainbow Reusable Sensors*) in the lower, right-hand corner of the screen. While a patient is monitored, the amount of time decreases until the remaining time shows "0 Min". Refer to the specific sensor DFU for additional information.

**NOTE:** *Sensor Time will not be displayed for SpHb Rainbow Adhesive Sensors because they have been designed for single patient use only. they have been designed and labeled for single patient use only.*

The time remaining shows on the display for 120 seconds in the following situations:

- The sensor is connected to the device and the device is turned on.
- The sensor is connected to the patient.
- The sensor is removed from the patient.

Additionally, the device displays the Sensor Time with one audible beep when the remaining time shows 4 hours, 2 hours, 1 hour and 0 minutes. At "0 Min", the sensor must be replaced.

**NOTE:** *The sensor will not expire while actively monitoring a patient.*

The user can view the remaining Sensor Time by entering the About menu and selecting "More". When using the Simplified User Interface, select the Next Menu Page icon and select the "?" icon to view the remaining Sensor Time.

## NUMERIC DISPLAY - PULSE RATE

The Pulse Rate displayed on the Radical-7 Pulse CO-Oximeter may differ slightly from the heart rate displayed on ECG monitors due to differences in averaging times. There may also be a discrepancy between cardiac electrical activity and peripheral arterial pulsation. Significant differences may indicate a problem with the signal quality due to physiological changes in the patient or one of the instruments or application of the sensor or patient cable. The pulsations from intra-aortic balloon support can cause the pulse rate displayed on the Pulse CO-Oximeter to be significantly different than the ECG heart rate.

## NUMERIC DISPLAY - SpCO

A stable SpCO reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion in the patient's fingertip (measurement site). Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion. Inaccurate measurements may be caused by:

- Levels of methemoglobin approximately 1.5% or above.
- Intravascular dyes such as indocyanine green or methylene blue.
- Abnormal hemoglobin levels.
- Low arterial perfusion.
- Low arterial oxygen saturation levels.
- Elevated Total Bilirubin levels.
- Motion artifact.

## NUMERIC DISPLAY - SpMet

A stable SpMet reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion in the patient's fingertip (measurement site). Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion. Inaccurate measurements may be caused by:

- Intravascular dyes such as indocyanine green or methylene blue.
- Low arterial perfusion.
- Low arterial oxygen saturation levels.
- Elevated Total Bilirubin levels.
- Motion artifact.

## NUMERIC DISPLAY - SpHb

A stable SpHb reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion at the measurement site. Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion. Inaccurate measurements may be caused by:

- Intravascular dyes such as indocyanine green or methylene blue.
- Low arterial perfusion.
- Low arterial oxygen saturation levels.
- Elevated Total Bilirubin levels.
- Motion artifact.

## NUMERIC DISPLAY - SpOC

A stable SpOC reading is associated with stable readings for both SpO<sub>2</sub> and SpHb which comes with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion at the measurement site. Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion. Inaccurate measurements may be caused by:

- Low arterial perfusion.
- Low arterial oxygen saturation levels.
- Elevated Total Bilirubin levels.
- Motion artifact.
- Elevated levels of carboxyhemoglobin.
- Elevated levels of methemoglobin.
- Severe anemia may cause erroneous SpOC readings.

## NUMERIC DISPLAY - (PI)

The perfusion index (PI) display provides a relative numeric indication of the pulse strength at the monitoring site. It is a calculated percentage of the pulsatile signal to non-pulsatile signal of arterial blood moving through the site. PI may be used to find the best perfused site and to monitor physiological changes in the patient. It displays an operating range of 0.02 percent to 20.00 percent. A percentage greater than 1.00 percent is desired. Extreme changes in the display number are due to motion artifact and changes in physiology and blood flow. The PI measurement is displayed as follows:

- ≤ 0.99 (2 decimal places)
- 1.0 to 9.9 (1 decimal place)
- ≥ 10 (0 decimal places)

## PLETH VARIABILITY INDEX - (PVI)

The pleth variability index (PVI) is a measure of the dynamic changes in the perfusion index (PI) that occur during the respiratory cycle. The calculation is accomplished by measuring changes in PI over a time interval where one or more complete respiratory cycles have occurred. PVI is displayed as a percentage (0-100%).

## SIGNAL INDICATION AND QUALITY INDICATOR (SIQ)

The Radical-7 Pulse CO-Oximeter display provides a visual indicator of the plethysmogram signal quality and an alert when the displayed SpO<sub>2</sub> values are not based on adequate signal quality. The signal quality indicator displayed on the Radical-7 Pulse CO-Oximeter is called the SpO<sub>2</sub> SIQ. The SpO<sub>2</sub> SIQ can be used to identify the occurrence of a patient's pulse and the associated signal quality of the measurement.

With motion, the plethysmographic waveform is often distorted and may be obscured by artifact. The SpO<sub>2</sub> SIQ, shown as a vertical line, coincides with the peak of an arterial pulsation. Even with a plethysmographic waveform obscured by artifact, the Radical-7 Pulse CO-Oximeter locates the arterial pulsation. The pulse tone (when enabled) coincides with the vertical line of the SpO<sub>2</sub> SIQ.

The height of the vertical line of the SpO<sub>2</sub> SIQ indicates the quality of the measured signal. A high vertical bar indicates that the SpO<sub>2</sub> measurement is based on a good quality signal. A small vertical bar indicates that the SpO<sub>2</sub> measurement is based on data with low signal quality. When the signal quality is very low the accuracy of the SpO<sub>2</sub> measurement may be compromised, and a "Low SpO<sub>2</sub> SIQ" message is displayed in the message area on the Radical-7 Pulse CO-Oximeter display. When the Low SpO<sub>2</sub> SIQ message appears, proceed with caution and do the following:


- Assess the patient.
- Check the sensor and ensure proper sensor application. The sensor must be well secured to the site for the Radical-7 Pulse CO-Oximeter to maintain accurate readings. Also, misalignment of the sensor's emitter and detector can result in smaller signals and cause erroneous readings.
- Determine if an extreme change in the patient's physiology and blood flow at the monitoring site occurred, (e.g. an inflated blood pressure cuff, a squeezing motion, sampling of an arterial blood specimen from the hand containing the pulse oximetry sensor, severe hypotension, peripheral vasoconstriction in response to hypothermia, medications, or an episode of Raynaud's syndrome.)
- With neonates or infants, check that the peripheral blood flow to the sensor site is not interrupted. Interruption, for example, may occur while lifting or crossing their legs during a diaper change.

After performing the above, if the Low SpO<sub>2</sub> SIQ message is displayed frequently or continuously, obtaining an arterial blood specimen for CO-Oximetry analysis may be considered to verify the oxygen saturation value.

## Low SpCO SIQ and Low SpMet SIQ

When the signal quality for SpCO and/or SpMet is very low, the accuracy of the SpCO and/or SpMet measurement(s) may be compromised, and a Low SpCO SIQ and/or Low SpMet SIQ message is displayed in the message area on the Radical-7 Pulse CO-Oximeter display. When the Low message(s) appear, proceed with caution and follow the steps listed in Section 4, *Signal Indication and Quality Indicator (SIQ)*.

## Low SpHb SIQ

When the SpHb signal quality is very low, the accuracy of the SpHb measurement may be compromised. A Low SpHb SIQ message is displayed in the message area on the Radical-7 Pulse CO-Oximeter display, and the parameter/measurement value will display dashes ("----") instead of a number value for both SpHb and SpOC. In addition, an  icon will appear in the Menu Icon bar where the Max/APOD icon normally is displayed. An available option is to acknowledge the Low SpHb SIQ state and display the number, with the understanding that the accuracy of the

value may be compromised. To acknowledge the Low SpHb SIQ state and display the number, press the  $\triangle$  icon. A numeric value will display for both SpHb and for SpOC. The “SpHb” parameter label will continue to flash to indicate the monitor is in a Low SpHb SIQ state.

If the user does not acknowledge the Low SpHb SIQ state, “---” will continue to be displayed instead of a number value. To access the Max/APOD button and change the Sensitivity setting in this situation when the  $\triangle$  icon is displayed, press the “next page” icon.

Note: Once the Low SpHb SIQ state is acknowledged, the  $\triangle$  icon will not be displayed again in the same monitoring session. The SpHb parameter label will still flash to indicate a Low SpHb SIQ state.

<sup>3</sup> Severinghaus JW, Spellman MJ. Pulse Oximeter Failure Thresholds in Hypotension and Vasoconstriction. *Anesthesiology* 1990; 73:532-537

## ACTIONS TO BE TAKEN

If the SpO<sub>2</sub>, SpCO, SpMet, or SpHb, SpOC, PVI, PI or pulse rate readings show significant differences, do the following:

- Make sure the emitter and detector are aligned directly opposite each other.
- Select a site where the distance between the emitter and detector is minimized.
- Wipe the sensor site with a 70% isopropyl alcohol pad or rubefacient cream (10-30% methyl salicylate and 2-10% menthol) for 20-30 seconds to increase perfusion. However, strong vasodilator creams, such as nitroglycerin paste, are not recommended.
- If possible, remove electrical noise sources such as electrosurgical units or other electrical/electronic equipment. If these solutions are not possible, operate the Pulse CO-Oximeter on battery power, or try plugging the Pulse CO-Oximeter into a different electrical outlet.
- If artificial nails or excessive fingernail polish are present, select another site or remove the polish/artificial nails.
- If possible, ensure that the sensor is placed in a location with low ambient or low strobing light. Although the Radical-7 with integrated Masimo Rainbow SET technology has significant immunity to ambient or strobing light, excessive ambient or excessive strobing light may cause readings to be incorrect.

**CAUTION:** IF ANY MEASUREMENT SEEMS QUESTIONABLE, FIRST CHECK THE PATIENT'S VITAL SIGNS BY ALTERNATE MEANS AND THEN CHECK THE PULSE CO-OXIMETER FOR PROPER FUNCTIONING.

## LOW PERFUSION

The Radical-7 Pulse CO-Oximeter displays a “Low Perfusion” message when there are very low amplitude arterial pulsations.

It has been suggested that at extremely low perfusion levels, pulse oximeters can measure peripheral saturation, which may differ from central arterial saturation<sup>3</sup>. This “localized hypoxemia” may result from the metabolic demands of other tissues extracting oxygen proximal to the monitoring site under conditions of sustained peripheral hypoperfusion. (This may occur even with a pulse rate that correlates with the ECG heart rate.)

**CAUTION:** IF THE LOW PERFUSION MESSAGE IS FREQUENTLY DISPLAYED, FIND A BETTER-PERFUSED MONITORING SITE. IN THE INTERIM, ASSESS THE PATIENT AND, IF INDICATED, VERIFY OXYGENATION STATUS THROUGH OTHER MEANS.

### SENSITIVITY

Three sensitivity levels enable a clinician to tailor the response of the Radical-7 to the needs of the particular patient situation. They are as follows:

- **Normal Sensitivity** – This is the recommended mode for patients that are experiencing some compromise in blood flow or perfusion. It is advisable for care areas where patients are observed frequently, such as an intensive care unit (ICU).
- **Adaptive Probe Off Detection (APOD)** – This is the recommended monitoring mode where there is a high probability of the sensor becoming detached. It is also the suggested mode for care areas where patients are not visually monitored continuously. This mode delivers enhanced protection against erroneous pulse rate and arterial oxygen saturation readings when a sensor becomes inadvertently detached from a patient due to excessive movement.
- **Maximum Sensitivity (MAX)** - This mode is recommended for patients with low perfusion or when the low perfusion message is displayed on the screen in APOD or normal sensitivity mode. This mode is not recommended for care areas where patients are not monitored visually, such as general wards. It is designed to interpret and display data at the measuring site when the signal may be weak due to decreased perfusion. When a sensor becomes detached from a patient, it will have compromised protection against erroneous pulse rate and arterial saturation readings.

**CAUTION:** WHEN USING THE MAXIMUM SENSITIVITY SETTING, PERFORMANCE OF THE SENSOR OFF DETECTION MAY BE COMPROMISED. IF THE INSTRUMENT IS IN THIS SETTING AND THE SENSOR BECOMES DISLODGED FROM THE PATIENT, THE POTENTIAL FOR FALSE READINGS MAY OCCUR DUE TO ENVIRONMENTAL 'NOISE' SUCH AS LIGHT, VIBRATION AND EXCESSIVE AIR MOVEMENT.



## Touch Key Control Button and Icons

The touch key control buttons are the four dark grey control buttons to the right of the Handheld display. To select a touch key icon, press and release the dark gray control button to the right of the icon, or below the icon in the vertical orientation.

On the Radical-7 Pulse CO-Oximeter display, four icons are shown on the right side or bottom of the LCD display

## Traditional User Interface

### FIRST PAGE

	<b>NEXT MENU PAGE</b>	Press the Next Menu Page button to access the second page of selections. Press and hold the button for 8 seconds to toggle between Traditional User Interface and the Simplified User Interface. Enter password when prompted (refer to Section 4, <i>Password Operation</i> ). The Radical-7 will retain this setting after a power cycle.
	<b>MENU ACCESS</b>	Press the Menu Access button to enter the main menu.
	<b>SENSITIVITY</b>	Press the Sensitivity button to toggle between the Normal, APOD and Maximum Sensitivity modes. Use the Normal Sensitivity setting for typical monitoring purposes. Use the APOD setting where there is a high probability of the sensor becoming detached. Use the Maximum Sensitivity setting for patients with low perfusion or when the low perfusion message is displayed on the screen in APOD or normal sensitivity mode. The default mode is APOD. <b>CAUTION:</b> WHEN USING THE MAXIMUM SENSITIVITY SETTING, THE PERFORMANCE OF THE SENSOR OFF DETECTION MAY BE COMPROMISED. <b>NOTE:</b> In "Custom" mode the instrument will remain in Normal or APOD setting after a power cycle. Maximum Sensitivity will automatically reset to Normal Sensitivity after a power cycle. In "Neo" or "Adult" mode the instrument will reset the sensitivity to the hospital specified setting (Normal or APOD) after a power cycle.
	<b>Low SpHb SIQ</b>	This button appears in the Menu bar where the Max/APOD button is normally displayed when the SpHb signal quality is very low. Press this button to acknowledge this low SIQ state and display the numeric value for SpHb.
	<b>TREND GRAPH</b>	Press the Trend Graph button to alternate between SpO <sub>2</sub> , pulse rate, SpMet, SpCO, SpHb, PI, PVI and SpOC Quick Trend displays.






### SECOND PAGE

	<b>NEXT MENU PAGE</b>	Press the Next Menu Page button to access the first page of selections. Press and hold the button for 8 seconds to toggle between Traditional User Interface and the Simplified User Interface. Enter password when prompted (refer to Section 4, <i>Password Operation</i> ). The Radical-7 will retain this setting after a power cycle.
	<b>TREND DISPLAY</b>	Press the Trend Display button to show the trend data on the display.
	<b>INCREASE LOUDNESS</b>	Press the Increase Loudness button to increase the volume of the pulse beep. Seven levels of volume exist.
	<b>DECREASE LOUDNESS</b>	Press the Decrease Loudness button to decrease the volume of the pulse beep.





## Simplified User Interface

By enabling the Simplified User Interface, users are exposed to only the most common Pulse CO-Oximeter features, while all the remaining settings remain available behind password protection.

### FIRST PAGE

	<b>NEXT MENU PAGE</b>	Press the Next Menu Page button to access the second page of selections. Press and hold the button for 8 seconds to toggle between Traditional User Interface and the Simplified User Interface. Enter password when prompted (refer to Section 4, <i>Password Operation</i> ). The Radical-7 will retain this setting after a power cycle.
	<b>ALARM MENU</b>	Press the Alarm Menu Access button to enter the alarm settings menu.
	<b>SENSITIVITY</b>	Press the Sensitivity button to toggle between the Normal, APOD and Maximum Sensitivity modes. Use the Normal Sensitivity setting for typical monitoring purposes. Use the APOD setting where there is a high probability of the sensor becoming detached. Use the Maximum Sensitivity setting for patients with low perfusion or when the low perfusion message is displayed on the screen in APOD or normal sensitivity mode. The default is APOD. <b>CAUTION:</b> WHEN USING THE MAXIMUM SENSITIVITY SETTING, THE PERFORMANCE OF THE SENSOR OFF DETECTION MAY BE COMPROMISED. <b>NOTE:</b> In "Custom" mode the instrument will remain in Normal or APOD setting after a power cycle. Maximum Sensitivity will automatically reset to Normal Sensitivity after a power cycle. In "Neo" or "Adult" mode the instrument will reset the sensitivity to the hospital specified setting (Normal or APOD) after a power cycle.
	<b>Low SpHb SIQ</b>	This button appears in the Menu bar where the Max/APOD button is normally displayed when the SpHb signal quality is very low. Press this button to acknowledge this low SIQ state and display the numeric value for SpHb.
	<b>TREND GRAPH</b>	Press the Trend Graph button to alternate between SpO <sub>2</sub> , pulse rate, SpMet, SpCO, SpHb, PI, PVI and SpOC Quick Trend displays.

### SECOND PAGE





	<b>NEXT MENU PAGE</b>	Press the Next Menu Page button to access the first page of selections. Press and hold the button for 8 seconds to toggle between Traditional User Interface and the Simplified User Interface. Enter password when prompted. The Radical-7 will retain this setting after a power cycle.
	<b>ABOUT MENU</b>	Press the About Menu button to access system information.
	<b>INCREASE LOUDNESS</b>	Press the Increase Loudness button to increase the volume of the pulse beep. Seven levels of volume exist.
	<b>DECREASE LOUDNESS</b>	Press the Decrease Loudness button to decrease the volume of the pulse beep.

## Navigating the Main Menu

When the main menu is accessed, the plethysmographic and Signal IQ waveform displays are replaced with the main menu items. The touch key icons, displayed along the right edge of the LCD display, are also replaced by the menu access icons. When the main menu is accessed, the monitor remains functional and the saturation and pulse rate numbers will continue to be displayed.





### MAIN MENU SELECTION

The top menu category uses the following four menu selections and touch key control buttons and icons.

	<b>EXIT</b>	Select the Exit icon to exit the main menu.
	<b>SELECT CATEGORY</b>	Select the Select Category icon to select the highlighted menu item and enter the next level menu.
	<b>PREVIOUS</b>	Select the Previous icon to scroll through the menu items without selecting them. Once a menu item is highlighted, enter the menu by pressing the Select Category icon.
	<b>NEXT</b>	Select the Previous icon to scroll through the menu items without selecting them. Once a menu item is highlighted, enter the menu by pressing the Select Category icon.





### MENU CATEGORIES

Once a menu category has been selected, a new set of menu selections and icons are displayed.

	<b>EXIT</b>	Select the Exit icon to exit the menu category and return to the previous menu.
	<b>EDIT PARAMETER</b>	Select the Edit Parameter icon to select the highlighted parameter/measurement for editing.
	<b>PREVIOUS</b>	Select the Previous icon to scroll through the parameters/measurements. Once a parameter/measurement is highlighted, edit the parameter/measurement by pressing the Edit Parameter icon.
	<b>NEXT</b>	Select the Next icon to scroll through the parameters/measurements. Once a parameter/measurement is highlighted, edit the parameter/measurement by pressing the Edit Parameter icon.

### EDITING A PARAMETER/MEASUREMENT

Once a parameter/measurement has been selected for editing, a new set of menu selections and icons are displayed.

	<b>EXIT</b>	Select the Exit icon to exit the parameter/measurement without making the new selections permanent.
	<b>ACCEPT</b>	Select the Accept icon to save the changes.
	<b>PREVIOUS</b>	Select the Previous icon to increase or toggle the parameter/measurement settings.
	<b>NEXT</b>	Select the Next icon to decrease or toggle the parameter/measurement settings.

## MENU TREE

<b>ALARMS</b>	SpO <sub>2</sub> High/Low limit	
	Pulse rate High/Low limit (bpm)	
	SpMet High/Low limit	
	SpCO High/Low limit	
	SpHb High/Low limit	
	PI High/Low limit	
	PVI High/Low limit	
	Silence	
	Volume	
	Delay (volume delay)	
	Mode	
<b>ROTATE SCREEN</b>	Landscape 1	
	Vertical 1	
	Landscape 2	
	Vertical 2	
<b>DISPLAY</b>	View	
	Trend	
	Language	
	Default	
	Vertical Layout	
<b>CLOCK</b>	Time (hour/minute/seconds)	
	Time display format	
	Day	
	Month	
	Year	
	Format (mm/dd/yy)	
	Display Clock	
<b>ABOUT</b>	Software Versions	
	More	Line Frequency
		Sensor Time
		NAC
		LMD
		CPI

CONFIG	Enter password (refer to Section 4 <i>Password Operation</i> )	Line Frequency (50 Hz, 60 Hz)
		Rapid Desat Limit (Off, -5, -10)
		Display Measurement (SpOC, None)
		SpHb Unit of Measurement (g/dL, mmol/L)
		SpHb Precision (0, 0.1 or 0.5)
		Arterial or Venous SpHb Value (SpHb, SpHb <sub>V</sub> )
		SpHb Cal
		Lock Alarm Volume (No, 3, 4)
		PVI Averaging (short, long)
GENERAL	Averaging Time	
	FastSat	
	Home Use	
	Interface Alarms SpO <sub>2</sub> /BPM	
	SatShare Numbers	
	Power Save	
	Smart Tone	
	PVI	
	SpHb Averaging (short, medium, long)	
	PI Averaging (short, long)	
3D ALARM	Desat Index	
	PI Delta	
OUTPUT	Serial	
	Analog 1	
	Analog 2	
	Nurse Call	
	Polarity	
SERVICE	Enter password (refer to Section 4 <i>Password Operation</i> )	
	Handheld Battery (Deep Discharge)	
	DS Battery (Deep Discharge)	

## Alarms

Check alarm limits each time the Pulse CO-Oximeter is used to ensure that they are appropriate for the patient being monitored. An audible alarm and a flashing alarm icon (and indicator light) will occur when an alarm limit is exceeded. It is best that the operator be within a minimum of 10 feet from the instrument.

MENU ITEMS	DESCRIPTION
SpO <sub>2</sub> HIGH LIMIT	The SpO <sub>2</sub> high alarm limit can be set anywhere between 2% and 99%, then "---" with a 1% step size. In the "----" (off) setting, the alarm can be turned off completely.
SpO <sub>2</sub> LOW LIMIT	<p>The SpO<sub>2</sub> low alarm limit can be set anywhere between 1% and 98%, with a 1% step size.</p> <p><b>NOTE:</b> The low alarm limit must be set below the high alarm setting. When the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit setting.</p> <p><b>NOTE:</b> The SpO<sub>2</sub> low limit cannot be set below the password protected minimum low SpO<sub>2</sub> alarm limit. See Section 4, Operation, Display for details.</p>
PULSE RATE HIGH LIMIT (BPM)	The pulse rate high alarm limit can be set anywhere between 35 BPM and 235 BPM, with a 5 BPM step size.
PULSE RATE LOW LIMIT (BPM)	<p>The pulse rate low alarm limit can be set anywhere between 30 BPM and 230 BPM, with a 5 BPM step size.</p> <p><b>NOTE:</b> The low alarm limit must be set below the high alarm setting. When the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit setting.</p>
SpMet HIGH LIMIT	The SpMet high alarm limit can be set anywhere between 1.0% to 99.5%, then "---". Between 1.0% and 2.0%, the step increment is 0.1%. Between 2.0% and 99.5%, the step increment is 0.5%.
SpMet LOW LIMIT	<p>The SpMet low alarm limit can be set as "---", or anywhere between 0.1% to 99%. Between 0.1% and 2.0%, the step increment is 0.1%. Between 2.0% and 99%, the step increment is 0.5%. In the "----" (off) setting, the alarm can be turned off completely.</p> <p><b>NOTE:</b> The low alarm limit must be set below the high alarm setting. If the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit setting.</p>
SpCO HIGH LIMIT	The SpCO high alarm limit can be set anywhere between 2% and 98%, then "---" with a 1% step size.

MENU ITEMS	DESCRIPTION
SpCO LOW LIMIT	<p>The SpCO low alarm limit can be set as "---", or anywhere between 1% and 97%, with a 1% step size. In the "----" (off) setting, the alarm can be turned off completely.</p> <p><b>NOTE:</b> The low alarm limit must be set below the high alarm setting. If the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit setting.</p>
SpHb HIGH LIMIT	<p>The SpHb high alarm limit can be set anywhere between 2.0 g/dl and 24.5 g/dl, then "----" with a 0.1 g/dl step size between 2.0 and 20.0, and a 0.5 g/dl step size between 20.0 and 24.5. In the "---" (off) setting, the SpHb High Alarm Limit Alarm is disabled. Factory default setting is 17 g/dl.</p>
SpHb LOW LIMIT	<p>The SpHb low alarm limit can be set as "---", or anywhere between 1.0 g/dl and 24 g/dl with a 0.1 g/dl step size between 1.0 and 20.0, and a 0.5 g/dl step size between 20.0 and 24.0. In the "---" (off) setting, the SpHb Low Alarm Limit Alarm is disabled. Factory default setting is 7 g/dl.</p> <p><b>NOTE:</b> The low alarm limit must be set below the high alarm setting. If the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit setting.</p>
PI HIGH LIMIT	<p>The PI high alarm limit can be set anywhere between 0.04 and 19, then "---" with a 0.01 step size between 0.04 and 0.10, a 0.10 step size between 0.10 and 1.0, and a 1.0 step size between 1.0 and 19. In the "---" (off) setting, the PI High Alarm Limit Alarm is disabled. Factory default setting is "----" (off).</p>
PI LOW LIMIT	<p>The PI low alarm limit can be set as "----", or anywhere between 0.03 to 18 with a .01 step size between 0.03 and 0.10, a 0.10 step size between 0.10 and 1.0, and a 1.0 step size between 1.0 and 18. In the "----" (off) setting, the PI Low Alarm Limit Alarm is disabled. Factory default setting is "---" (off).</p> <p><b>NOTE:</b> The low alarm limit must be set below the high alarm setting. If the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit setting.</p>
PVI HIGH LIMIT	<p>The PVI high alarm limit can be set anywhere between 2 and 99, then "----" with a 1 step size between 2 and 99. In the "----" (off) setting, the PVI High Alarm Limit Alarm is disabled. Factory default setting is "---" (off).</p>
PVI LOW LIMIT	<p>The PVI low alarm limit can be set as "---", or anywhere between 1 and 98 with a 1 step size. In the "----" (off) setting, the PVI Low Alarm Limit Alarm is disabled. Factory default setting is "----" (off).</p> <p><b>NOTE:</b> The low alarm limit must be set below the high alarm setting. If the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit setting.</p>

**Alarms (continued)**

MENU ITEMS	DESCRIPTION
<b>SILENCE</b>	<p>This menu allows the user to set the alarm silence period for SpO<sub>2</sub>, SpMet, SpCO, SpHb, PI, PVI and pulse rate. An alarm is silenced by pressing the Alarm Silence button on the front panel.</p> <p><b>30, 60, 90, 120 SECONDS</b></p> <p>The alarm silence can be set for these durations. As an indicator that the alarm system is silenced, the Alarm Status Indicator is shown as a bell with a slash through it. A timer is shown next to the bell indicating the remaining alarm silence duration.</p> <p>NOTE: The alarm silence period is reset to 120 seconds (or 90 seconds in neonatal mode) upon power cycle, except when the Radical-7 is set to operate in the Home mode.</p> <p><b>ALL MUTE</b></p> <p>All patient alarm conditions are silenced. Only system alarms will be indicated by an audible alarm. As an indicator that the system is set to All Mute, the Alarm Status Indicator is shown as a bell with a slash through it.</p> <p><b>ALL MUTE WITH AUDIBLE REMINDER</b></p> <p>All patient alarm conditions are silenced. Only system alarms will be indicated by an audible alarm. As a reminder, a single audible alarm will occur every three minutes. As an indicator that the system is set to All Mute, the Alarm Status Indicator is shown as a bell with a slash through it.</p>

**WARNING:** IF AN ALARM CONDITION OCCURS WHILE THE ALARM SILENCE PERIOD IS SET TO ALL MUTE, THE ONLY ALARM INDICATIONS WILL BE VISUAL DISPLAYS AND SYMBOLS RELATED TO THE ALARM CONDITION. NO ALARM TONE WILL SOUND.

**NOTE:** With the Handheld instrument, if there is a loss of power for any length of time, check the alarm settings. Generally, the alarm limit settings will be set back to the User set defaults if the user previously selected YES in the Save Last option under the Display menu. If the user has not utilized this option, then they will be set back to the factory defaults.

MENU ITEMS	DESCRIPTION
<b>VOLUME</b>	<p>This menu allows the user to set the alarm volume. Four levels are available: level 1 being the softest and level 4 being the loudest. The instrument retains the Alarm Volume setting upon a power cycle.</p> <p><b>NOTE:</b> For home use, set the alarm level to level 4.</p>



Alarms (continued)

DELAY	<p>This menu allows the users to set an audible saturation delay. The delay can be set to either 0, 5, 10 or 15 seconds. The delay setting only affects saturation alarms indications.</p> <p><b>NOTE:</b> In "Custom" mode (see Section 4, Operation) the instrument will retain the Alarm Delay setting after a power cycle. In "Neo" or "Adult" mode (see Section 4, Operation) the instrument will reset the Alarm Delay to the hospital specified setting after a power cycle.</p>				
MODE	<p>The Radical-7 stores three types of modes: Adult, Neonatal or Custom limits. Adult and Neonatal must be initially set and enabled (via password protected screen, see Section 4, Password Operation) before they can be selected.</p> <p><b>ADULT</b> Any changes to settings on the Alarm menu will be reset to pre-defined Adult defaults after a power cycle.†</p> <p><b>CUSTOM</b> Any changes to settings on the Alarm menu will be retained after a power cycle.*</p> <p><b>NEO</b> Any changes to settings on the Alarm menu will be reset to pre-defined Neonatal defaults after a power cycle.†</p>				
	TYPES	SpO <sub>2</sub> (High)	SpO <sub>2</sub> (Low)	PULSE RATE (High)	PULSE RATE (Low)
	ADULT LIMITS†	Off	90%	140 BPM	50 BPM
	NEONATAL LIMITS†	100%	90%	180 BPM	100 BPM
	CUSTOM LIMITS*	Off*	90%*	140 BPM*	50 BPM*
	<p><b>NOTE:</b> Limits are set at the factory to the values listed in this table. *Once Custom values are changed by the user, they will be retained after a power cycle. †Adult and Neo settings can be changed (via a password protected screen, see Section 4, Password Operation) to specific hospital/instrument requirements. If the settings are changed, then any values changed by the user will be returned to the instrument's default values after it is powered down.</p>				

## Rotate Screen

MENU ITEMS	DESCRIPTION
LANDSCAPE 1	The viewing screen will be in a horizontal fashion when the Radical-7 is in the upright, horizontal position.
VERTICAL 1	The viewing screen will be in a vertical fashion when the Radical-7 is in the upright, vertical position.
LANDSCAPE 2	The viewing screen will be in an inverted horizontal fashion (rotated 180°) when the Radical-7 is in the upright, horizontal position.
VERTICAL 2	The viewing screen will be in an inverted vertical fashion (rotated 180°) when the Radical-7 is in the upright, vertical position.

## Display

MENU ITEMS	DESCRIPTION
VIEW	<p>Five views are available: PVI Pleth and Signal IQ, PVI Pleth, Pleth and Signal IQ, Numbers and Pleth Only.</p> <p><b>PVI PLETH + SIGNAL IQ / PLETH + SIGNAL IQ</b></p> <p>Shows the SpO<sub>2</sub> and pulse rate numbers on the left or top of the screen. The PVI plethysmograph-Signal IQ and plethysmograph-Signal IQ waveforms are on the right, two-thirds or bottom of the screen. The screen also indicates the signal strength of the measured signal as a perfusion index (PI). The PI is calculated as the relation of arterial pulsatile signal to the non-pulsatile signal component. The percentage measurements of methemoglobin (SpMet) and carboxyhemoglobin (SpCO) are displayed in the middle upper third of the screen above the PI measurement. The PVI measurement is displayed under the SpCO measurement.</p> <p><b>PVI PLETH / PLETH ONLY</b></p> <p>Shows the SpO<sub>2</sub> and pulse rate numbers on the left or top of the screen. The PVI plethysmograph and plethysmographic waveform are on the right, two-thirds or bottom of the screen. The screen also indicates the signal strength of the measured signal as a perfusion index (PI). The PI is calculated as the relation of arterial pulsatile signal to the non-pulsatile signal component. The percentage measurements of methemoglobin (SpMet) and carboxyhemoglobin (SpCO) are displayed in the middle upper third of the screen above the PI measurement. The PVI measurement is displayed under the SpCO measurement.</p> <p><b>NUMBERS</b></p> <p>Shows the SpO<sub>2</sub> and pulse rate numbers and the signal IQ in the form of a pulse bar on the screen. The screen also indicates the signal strength of the measured signal as a perfusion index (PI). The PI is calculated as the relation of arterial pulsatile signal to the non-pulsatile signal component. The percentage measurements of methemoglobin (SpMet) and carboxyhemoglobin (SpCO) are displayed in the middle of the screen in line with the PI measurement. The PVI measurement is displayed under the PI measurement.</p>

MENU ITEMS	DESCRIPTION
TREND	<p>This allows the user to select and view the Trend data between:</p> <ul style="list-style-type: none"> <li>■ %SpO<sub>2</sub></li> <li>■ Pulse Rate (BPM)</li> <li>■ Perfusion Index (PI)</li> <li>■ Pleth Variability Index (PVI)</li> <li>■ Methemoglobin (MET)</li> <li>■ Carboxyhemoglobin (CO)</li> <li>■ Total Hemoglobin (HB)</li> <li>■ SpOC (OC)</li> </ul> <p><b>NOTE:</b> These parameters/measurements are viewed when utilizing the Trend Display function and not the Trend Graph function.</p>
LANGUAGE	<p>Allows the user to select the language displayed on the screen.</p>
DEFAULT	<p>Allows the user to select user mode or reset the settings to factory defaults.</p> <p><b>NOTE:</b> A password is required to access these menu options. Refer to Section 4, Password Operation</p> <p><b>LOW % SpO<sub>2</sub> LIMIT</b>          Allows the qualified user to set a custom default minimum low SpO<sub>2</sub> limit. When set, it will be the lowest value to which the low SpO<sub>2</sub> alarm limit can be set. For example, if the limit is set to 85%, then it cannot be set lower than 85% through the Main Alarm menu. The instrument will return to this setting after a power cycle.</p> <p><b>SAVE LAST</b>          This allows the user to either use Custom setting or Adult/Neonatal settings. Select "Yes" to use custom settings.</p> <p><b>SAVE AS ADULT</b>          Store current settings as Adult default setting.</p> <p><b>SAVE AS NEO</b>          Store current settings as Neonatal default setting.</p> <p><b>RESTORE FACTORY</b>          Recall factory setting for Custom, Adult and Neonatal.</p>
VERTICAL LAYOUT	<p><b>DEFAULT</b>          Displays the alarm parameters/measurements in vertical sequence of SpO<sub>2</sub>, SpHb, SpMet, SpOC, SpCO, BPM, PVI and PI.</p> <p><b>TRADITIONAL</b>          Displays the alarm parameters/measurements in vertical sequence of SpO<sub>2</sub>, BPM, PVI PI, SpHb, SpMet, SpOC and SpCO.</p>

## Clock

MENU ITEMS	DESCRIPTION
TIME	Set the time - hour, minutes and seconds - in 24 hour format.
TIME FORMAT	Set the format of the time display as it will be shown on the front panel. Available options are 12 hour (default) and 24 hour display.
DAY	Set the numerical day.
MONTH	Set the numerical month.
YEAR	Set the numerical year.
DAY FORMAT	Set the format of the date display as it will be shown on the front panel. Available options are mm/dd/yy (default) and dd/mm/yy.
DISPLAY CLOCK	Set to display the date and time on the front panel by selecting <b>YES</b> or <b>NO</b> .

## About

This displays the copyright and software versions of the Handheld and Docking Station.

MENU ITEMS	DESCRIPTION
MORE	<b>LINE FREQUENCY</b> - Allows the user to view the current Line Frequency setting without a password.
	<b>SENSOR TIME</b> - Allows the user to view the amount of sensor time remaining for SpHb Rainbow Reusable sensors.
	<b>NAC</b> - Available battery life
	<b>LMD</b> - Battery capacity
	<b>CPI</b> - Number of charge cycles

## Config

MENU ITEMS	DESCRIPTION
<b>ENTER PASSWORD</b> See Section 4, <i>Password Operation</i>	Line Frequency Set to 50 or 60 Hz. Set to match regional power line frequency to allow for cancellation of noise introduced by fluorescent lights and other sources. Factory default is 60 Hz.
	Rapid Desat Limit Set to Off, -5 or -10. When set to -5% or -10%, this feature overrides the Alarm Delay (audible alarms silenced) and the instrument will alarm if SpO <sub>2</sub> rapidly falls to 5% or 10% below the low alarm limit. Factory default is -5%.
	Display Measurement Set to SpOC or None. Display Measurement must be set to SpOC for SpOC to show on the screen and in the Trend Setup screen. Factory Default is SpOC.
	SpHb UOM Set to g/dL or mmol/L Display total hemoglobin (SpHb) Unit of Measurement data as g/dL (grams per deciliter) or mmol/L (millimoles per liter). Factory default is g/dL.

MENU ITEMS		DESCRIPTION
<b>ENTER PASSWORD</b> See Section 4, <i>Password Operation</i>	SpHb Precision	Set to 0 (whole numbers), 0.1 or 0.5 increments. This feature allows the user to set the decimal for SpHb. Factory default is 0.1.
	SpHb Cal	Set to SpHb or SpHb <sub>v</sub> . This feature provides an Arterial (SpHb) or Venous (SpHb <sub>v</sub> ) value that displays on the main screen. <i>NOTE: The hemorheologic profile of arterial and venous blood samples can vary<sup>1</sup>. To accommodate this difference, the Radical-7 provides the option of displaying a SpHb parameter that is based on either Arterial or Venous SpHb laboratory blood sample data.</i> Changes to SpHb are included in output data. SpOC calculation will always be based on the arterial SpHb.
	Lock Alarm Volume	Set to No, 3 or 4. When set to 3 or 4, 3 or 4 shows dimly lit in the Alarm Volume section of the Alarms Menu screen and cannot be changed. Factory Default is No.
	PVI Averaging	The signal averaging algorithm can be set to short or long. Factory default is long.

## CAUTION:

CHANGING THE SpHb CAL, THE DATE AND TIME OF THE SYSTEM CLOCK, OR THE TREND PERIOD CLEARS THE DATA IN THE TREND MEMORY.

<sup>1</sup>F.C. Mokken. Differences in peripheral arterial and venous hemorheologic parameters, Ann Hematol (1996) 73:135-13

## General

MENU ITEMS	DESCRIPTION
<b>AVERAGING TIME</b>	The signal averaging time of this instrument can be set to: 2, 4, 8, 10, 12, 14 and 16 seconds*. *With FastSat the averaging time is dependent on the input signal. For the 2 and 4 second settings, the averaging times may range from 2-4 and 4-6 seconds, respectively.
<b>FASTSAT</b>	Select <b>Yes</b> to activate the FastSat algorithm. In the 2 and 4 seconds averaging mode, the FastSat algorithm is automatically enabled.
<b>HOME USE</b>	Set the Radical-7 to the Home Mode. The Radical-7 will remain in the Home Mode until the <b>No</b> setting is selected. A password is required to activate or deactivate this mode. See Section 4, <i>Home Mode Operation</i> , for a detailed description.

MENU ITEMS	DESCRIPTION
<b>INTERFACE ALARMS SpO<sub>2</sub>/BPM</b>	<p>During SatShare, Patient SafetyNet, Philips Vuelink, Spacelabs Flexport and RadNet operation, the audible alarms for SpO<sub>2</sub> can be enabled or disabled by selecting Yes or No.</p> <p>All other parameters/measurements will be actively monitored by the instrument.</p> <p>The Rainbow parameters/measurements cannot be turned off with this feature.</p> <p><b>Yes setting:</b> allows SpO<sub>2</sub> and pulse rate audible alarms at the Radical-7 and the interfaced system.</p> <p><b>No setting:</b> mutes the SpO<sub>2</sub> and pulse rate audible alarms at the Radical-7 while allowing SpO<sub>2</sub> and pulse rate audible alarm alerts at the interfaced system. The "No" setting prevents both systems (Radical-7 and interfaced system) from producing audible alarms at the same time.</p> <p><b>NOTE:</b> The Radical-7 reverts to Interface Alarm SpO<sub>2</sub>/BPM "Yes" during power interruptions or when the SatShare connection is lost or the instrument becomes separated from the docking station. This ensures that the Radical-7 provides audible alarms for SpO<sub>2</sub> and pulse rate when the connection to the interfaced system becomes compromised.</p>
<b>SATSHARE NUMBERS</b>	<p>During SatShare operation the saturation and pulse rate measurements can be displayed on the Radical-7 by selecting a SatShare Numbers setting of <b>Yes</b>.</p>
<b>POWER SAVE</b>	<p>Select <b>Yes</b> to maximize battery-operating time of the Radical-7 while powered by the Handheld battery or optional Docking Station battery. Selecting <b>Yes</b> will disable Docking Station functions such as SatShare, Serial and Analog output. Selecting <b>No</b> will activate these Docking Station functions while operating on battery power. (While operating in the Power Save mode, a power cycle of the Radical-7 may be required to activate the Docking Station again after it has been disabled.)</p> <p><b>NOTE:</b> Handheld devices with software version 7.6 or greater will automatically activate the power save mode when the handheld device is docked into a docking station that is not connected to AC power.</p>
<b>SMART TONE</b>	<p>Select <b>Yes</b> to activate the SmartTone function. This will allow the audible pulse to continue to beep when the pleth graph shows signs of motion. Select <b>NO</b> to turn off SmartTone.</p>
<b>PVI</b>	<p>Select <b>Yes</b> to display the PVI measurement. The PVI will display numerically on the main screen and also will allow to the user to change the maximum and minimum PVI settings in the Trend Setup menu. Select <b>NO</b> to deselect the measurement.</p>
<b>SpHb AVERAGING</b>	<p>SpHb Averaging can be set to Long, Medium, or Short.</p>
<b>PI AVERAGING</b>	<p>The signal averaging algorithm can be set to short or long. The default is short.</p>

## 3D ALARM

Refer to Section 5, *3D ALARM*.

## Output

**NOTE:** The output menu selections are only available when the Radical-7 Handheld is interfaced to the Docking Station.

MENU ITEMS	DESCRIPTION
<b>SERIAL</b>	<p>The following serial output modes are supported. All serial output is RS-232 based. See the interface specifications in Section 7, <i>Specifications</i>.</p> <p><b>ASCII 1</b> ASCII text data is sent to the serial interface at one-second intervals. The ASCII text includes: date and time stamp, SpO<sub>2</sub>, pulse rate, PI, SpMet, SpCO, SpHb, SpOC, and alarm and exception values. All text is single line followed by a line feed character and a carriage return.</p> <p><b>ASCII 2</b> ASCII text data is sent to the serial interface following a query from the connecting computer. This mode will need to be active for data output to a monitoring system.</p> <p><b>BINARY</b> Compressed binary data is sent to the serial interface following a query from the connecting computer.</p> <p><b>PHILIPS VUELINK</b> SpO<sub>2</sub>, pulse rate and plethysmographic waveform data are sent in Philips VueLink format to the serial port.</p> <p><b>SPACELABS FLEXPORT</b> SpO<sub>2</sub>, pulse rate and plethysmographic waveform data are sent in Spacelabs Flexport format to the serial port.</p>
<b>ANALOG1 OR ANALOG 2</b>	<p><b>SpO<sub>2</sub> 0 - 100%</b> Scales the saturation measurement with 0% being equal to 0 Volt and 100% equal to 1 Volt.</p> <p><b>SpO<sub>2</sub> 50 - 100%</b> Scales the saturation measurement with 50% being equal to 0 Volt and 100% equal to 1 Volt.</p> <p><b>PULSE RATE</b> Scales the pulse rate measurement with 0 BPM being equal to 0 Volt, and 250 BPM equal to 1 Volt.</p> <p><b>PLETH</b> Traces the plethysmographic waveform as shown on the Radical-7 display.</p> <p><b>SIGNAL IQ</b> Traces the Signal IQ waveform as shown on the Radical-7 display. A full scale Signal IQ signal (100%) is represented as 1 Volt, while a zero Signal IQ signal (0%) is represented as 0 Volt.</p>

**Output (continued)**

MENU ITEMS	DESCRIPTION
<b>ANALOG1 OR ANALOG 2 (CONTINUED)</b>	<p><b>0V OUTPUT</b> A 0 Volt calibration signal is mapped to the analog output. Use this signal for calibration of recording instruments. (0 Volts represents a saturation of 0% and a pulse rate of 0 bpm).</p> <p><b>1V OUTPUT</b> A 1 Volt calibration signal is mapped to the analog output. Use this signal for calibration of recording instruments. (1 Volt represents a saturation of 100% and a pulse rate of 250 bpm).</p>
<b>NURSE CALL</b>	<p><b>ALARMS</b> The nurse call output will be activated based on alarm events.</p> <p><b>LOW SIGNAL IQ</b> The nurse call output will be activated based on Low Signal IQ events.</p> <p><b>ALARM &amp; SIGNAL IQ</b> The nurse call output will be activated based on alarm and Low Signal IQ events.</p>
<b>POLARITY</b>	<p><b>NORMAL</b> Standard polarity. See Section 7, Analog output / nurse call specifications.</p> <p><b>INVERT</b> This setting reverses the Normally Open and Normally Closed contacts. See Section 7, Analog output / nurse call specifications.</p>

**CAUTION:** TO AVOID EXCESSIVE BATTERY DISCHARGING, DO NOT CONNECT ANY EQUIPMENT TO THE SERIAL PORT ON THE BACK PANEL UNLESS THE RADICAL-7 IS CONNECTED TO THE AC POWER FROM THE WALL OUTLET.



## Service

**NOTE:** The Service menu selections are only available when the Radical-7 Pulse CO-Oximeter Handheld is interfaced to the Docking Station.

Only qualified Biomedical or Clinical Engineering department personnel should access the service menu. See Section 4, *Password Operation*, on how to enter the password.

MENU ITEMS	DESCRIPTION
HANDHELD BATTERY DISCHARGE	To deep discharge the Handheld battery, select this menu item. See Section 9, <i>Battery Operation and Maintenance</i> , for more information.
DS BATTERY DISCHARGE	To deep discharge the optional Docking Station battery, select this menu item. See Section 9, <i>Battery Operation and Maintenance</i> , for more information.

The discharge cycle will take approximately 16 hours to complete for the Handheld battery. The Docking Station battery will take approximately 30 hours to complete. A message will appear in the service screen when the discharge cycle is complete. The batteries will be fully charged after completion of the cycle.

When deep discharge is started, the backlight will automatically revert the default handheld battery powered level. Wait until the message changes from "In Progress" to "Done".

**NOTE:** In order for the discharge cycle to be properly completed, AC power must be supplied to the instrument throughout the cycle.

**WARNING:** WHEN DEEP-DISCHARGING THE HANDHELD OR DOCKING STATION BATTERY, MAKE SURE THAT THE INSTRUMENT HAS BEEN REMOVED FROM SERVICE UNTIL FULL BATTERY CAPABILITY CAN BE RESTORED.

## Trend Display

Once the Trend Display touch key icon is selected, the trend data is displayed on the main screen. The Radical-7 Pulse CO-Oximeter stores one data set of SpO<sub>2</sub>, pulse rate, SpMet, SpCO, SpHb, SpOC, PI, PVI and system messages in a dedicated memory area. Depending on the Trend Period, a setting for how often the data is stored in the trend memory, the Radical-7 Pulse CO-Oximeter can store between 72 hours and > 10 days of trend data. The Radical-7 Pulse CO-Oximeter also employs a sophisticated data compression scheme. The actual amount of trend data that is stored is dependent on the type of data that is collected.

The Radical-7 Pulse CO-Oximeter only stores data in the trend memory while the instrument is turned on, and the trend data remains in memory until the memory is full, or is cleared by the user.

**CAUTION:** CHANGING THE DATE AND TIME OF THE SYSTEM CLOCK, OR CHANGING THE TREND PERIOD, WILL ALSO CLEAR THE DATA IN THE TREND MEMORY.

The following table outlines the trend capacity for sample Trend Period settings:

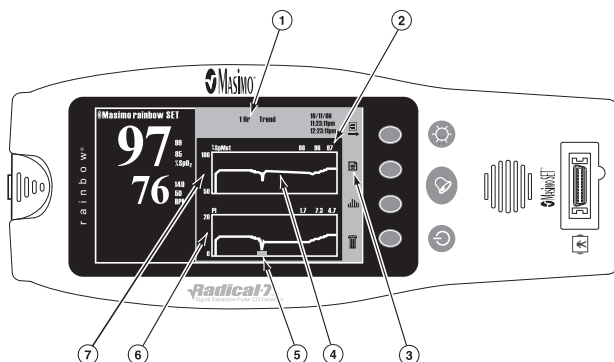
TREND PERIOD	TREND MEMORY CAPACITY
2 SECONDS	UP TO 72 HOURS (APPROXIMATELY 3 DAYS)
10 SECONDS	> 10 DAYS

The Trend Display can be configured to display one or two of any of the available trend parameters/measurements (SpO<sub>2</sub>, SpMet, SpCO, SpHb, SpOC, pulse rate, PI or PVI) selected by the user. The instrument is storing all parameters/measurements in trend memory, but can only display one or two user selected parameters/measurements at any one time. The Trend Display can be adjusted to the desired parameter/measurement by selecting **Trend** from the Main, Display Menu.

### TREND AUTO SCALE

The Radical-7 can be set to automatically change the trend data field by adjusting the area (scale) of the graph that is shown. The scale of the trended graph is adjusted to focus on the values of the data presented. The movable area of focus allows improved data viewing. As the data trends up or down, the Radical-7 automatically adjusts the scale (or viewing area) to maintain the data within the field of view.

### TREND DISPLAY SCREEN



## TREND DISPLAY SCREEN (CONTINUED)





①	The top line on the trend display shows the time scale of the trend graph, followed by the starting date, starting time and end time of the data set that is displayed on the screen.
②	The second line of the display shows the minimum, maximum and average SpO <sub>2</sub> , SpMet, SpCO, SpHb, SpOC, PI, pulse rate or PVI measurements contained in the displayed data set (excluding zero measurements).
③	The scale range of SpO <sub>2</sub> , BPM, PI, SpMet, SpCO, SpHb, SpOC or PVI graphs can be set in the Trend Setup menu. For other settings, see Trend Setup in the following pages.
④	A vertical line on the trend graph indicates the averaged data, while the horizontal line shows beginning and ending periods of the trend or when the sensor was removed from the patient.
⑤	A dimly lit box or line located on the bottom axis of the saturation graph indicates a period of time for which the Low Signal IQ indicator was active, indicating the signal quality was very low and the accuracy of the measurement may have been compromised.
⑥ ⑦	The available trend graphs show two of the desired trend parameters/measurements displayed versus time.

By default, the trend display automatically refreshes, at a rate of once every 10 seconds, to show the latest measured SpO<sub>2</sub>, SpMet, SpCO, SpHb, SpOC, PI, PVI or pulse rate data. This feature is only available while the trend view is 2 hours or less, and the latest measured data is shown. If the user scrolls through the data set to display previously recorded trend data, or if the trend scale is greater than 2 hours, the trend display will time out after 1 minute of inactivity (i.e. the user does not press any of the touch key control buttons) and the normal Radical-7 Pulse CO-Oximeter display will be shown.





## NAVIGATING THE TREND DISPLAY

In the Trend Display view there are a total of 10 touch key icon selections on 3 pages of menu selections. These menu screens are not accessible when using the Simplified User Interface.





### FIRST PAGE

	<b>NEXT MENU PAGE</b>	Press the Next Menu Page button to access the next page of menu selections.
	<b>EXIT</b>	Press the Exit button to return to the normal display screen.
	<b>SCROLL RIGHT</b>	Press the Scroll Right button to scroll through the data set. The display scrolls by ½ the selected time scale. For example if a 2 hr display view is selected, then pressing the Scroll Right button will scroll the displayed data by 1 hr to the right.
	<b>SCROLL LEFT</b>	Press the Scroll Left button to scroll through the data set. The display scrolls by ½ the selected time scale. For example if a 2 hr display view is selected, then pressing the Scroll Left button will scroll the displayed data by 1 hr to the left.

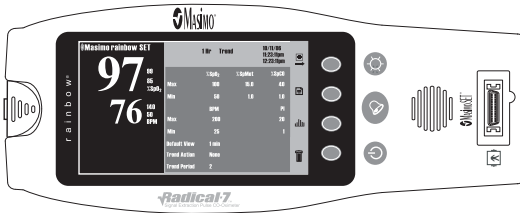
## SECOND PAGE

	<b>NEXT MENU PAGE</b>	Press the Next Menu Page button to access the next page of menu selections.
	<b>ZOOM</b>	Press the Zoom button to change the time scale of the trend view. The available time scales are 24 hrs, 12 hrs, 8 hrs, 4 hrs, 2 hrs, 1 hr, 30 minutes, 10 minutes, 1 minute and 20 seconds. The Zoom button uses the last recorded data point as the zoom reference point. The last recorded data point is always shown as the right-most data point on the display.
	<b>ZOOM FROM LEFT</b>	Press the Scroll Right button to scroll through the data set. The display scrolls by ½ the selected time scale. For example if a 2 hr display view is selected, then pressing the Scroll Right button will scroll the displayed data by 1 hr to the right.
	<b>ZOOM FROM RIGHT</b>	Press the Scroll Left button to scroll through the data set. The display scrolls by ½ the selected time scale. For example if a 2 hr display view is selected, then pressing the Scroll Left button will scroll the displayed data by 1 hr to the left.

## THIRD PAGE

	<b>NEXT MENU PAGE</b>	Press the Next Menu Page button to return to the first page of menu selections.
	<b>TREND SETUP</b>	Press the Trend Setup button to enter the Trend Setup Menu.
	<b>HISTOGRAM</b>	Press the Histogram button to display the selected data set (the data set shown in the trend view) in histogram format.
	<b>CLEAR TREND DATA</b>	Press the Clear Trend Data button to clear the data stored in the trend memory.

## TREND SETUP



This menu allows the user to set the default trend settings or download the trend data. The default settings are used to scale the trend graphs when the trend data button, located on the main display, is accessed.

MENU ITEMS	DESCRIPTION
%SpO <sub>2</sub> AUTO SCALE	Sets the %SpO <sub>2</sub> scale to automatically adjust to the data presented.
%SpO <sub>2</sub> MAX SCALE	Sets the maximum scale of the SpO <sub>2</sub> trend graph.
%SpO <sub>2</sub> MIN SCALE	Sets the minimum scale of the SpO <sub>2</sub> trend graph.
PR AUTO SCALE (BPM)	Sets the PR scale to automatically adjust to the data presented.
PR MAX SCALE (BPM)	Sets the maximum scale of the pulse rate trend graph.
PR MIN SCALE (BPM)	Sets the minimum scale of the pulse rate trend graph.
PI AUTO SCALE	Sets the PI scale to automatically adjust to the data presented.
PI MAX SCALE	Sets the maximum scale of the PI trend graph.
PI MIN SCALE	Sets the minimum scale of the PI trend graph.
%SpMet AUTO SCALE	Sets the %SpMet scale to automatically adjust to the data presented.
%SpMET MAX SCALE	Sets the maximum scale of the SpMet trend graph.
%SpMET MIN SCALE	Sets the minimum scale of the SpMet trend graph.
%SpCO AUTO SCALE	Sets the %SpCO scale to automatically adjust to the data presented.
%SpCO MAX SCALE	Sets the maximum scale of the SpCO trend graph.
%SpCO MIN SCALE	Sets the minimum scale of the SpCO trend graph.
SpHb AUTO SCALE	Sets the SpHb scale to automatically adjust to the data presented.
SpHb MAX SCALE	Sets the maximum scale of the SpHb trend graph.
SpHb MIN SCALE	Sets the minimum scale of the SpHb trend graph.
SpOC AUTO SCALE	Sets the SpOC scale to automatically adjust to the data presented.
SpOC MAX SCALE	Sets the maximum scale of the SpOC trend graph.
SpOC MIN SCALE	Sets the minimum scale of the SpOC trend graph.
PVI AUTO SCALE	Sets the PVI scale to automatically adjust to the data presented.
PVI MAX SCALE	Sets the maximum scale of the PVI trend graph.
PVI MIN SCALE	Sets the minimum scale of the PVI trend graph.
DEFAULT VIEW	Selects the default time scale of the trend view. This setting only selects the time scale of the trend view when the trend data is initially displayed, (i.e. when the trend data is initially accessed). The selections are 24 hrs, 12 hrs, 8 hrs, 4 hrs, 2 hrs, 1 hr, 30 minutes, 10 minutes, 1 minute and 20 seconds.

## TREND SETUP (CONTINUED)

MENU ITEMS	DESCRIPTION
TREND ACTION	<b>SERIAL DUMP</b> To send all the data that is stored in trend memory to the serial port select the Serial Dump option. Use this option to communicate the stored data set to trend graphing software applications.
	<b>ANALOG DUMP</b> To send all the data that is stored in the trend memory to the analog output select the Analog Dump option. Use this option to print the trend information on an analog chart recorder.
	<b>PRINT</b> To print the trend data that is shown in the Trend View select the Print option. The trend data is first printed in histogram format, followed by a table of data that shows the time and date stamp of a trend record, and the SpO <sub>2</sub> , pulse rate, SpMet, SpCO, SpHb, SpOC, PVI and PI measurements. Each trend record is printed on a single line followed by a carriage return and line feed character.
TREND PERIOD	The Trend Period setting determines how often a set of SpO <sub>2</sub> , pulse rate, SpMet, SpCO, SpHb, SpOC, PVI and PI data points are stored in trend memory. A setting of 2, for example, sets the Radical-7 Pulse CO-Oximeter to store one set of SpO <sub>2</sub> , pulse rate, SpMet, SpCO, SpHb, SpOC, PVI and PI measurements every 2 seconds, resulting in a minimum trend capacity of 72 hours. A setting of 10, for example, sets the Radical-7 Pulse CO-Oximeter to store one set of data points every 10 seconds, resulting in a typical trend storage capacity of > 10 days.
SpHb TREND	When the Radical-7 is configured with SpHb and a SpHb compatible sensor is connected, the SpHb Trend-Graph can automatically display. Select Yes (default) to display this feature or No to have the feature not display.

**NOTE:** Since the Radical-7 Pulse CO-Oximeter employs a sophisticated data compression scheme, the actual trend capacity is dependent on the type of data that is collected.

## HISTOGRAM

The figure below is an example of the display output of the Histogram function. The Histogram displays the trend data of selected parameters as numerical percentages shown in specific ranges.



## Trend Setup and Use

### INTRODUCTION

The Radical-7 can store up to 72 hours of trend data captured at 2 second intervals. The trend data can then be transferred to a PC for evaluation.

A serial cable is required to connect the Radical-7 to a PC.

Trend data is stored in non-volatile memory, so it is not erased when the instrument is shut off.

A trend data download is initiated using the TrendCom utility which downloads the trend data and saves it to an ASCII text (.out) file with an output delimiter option.

### TRENDCOM UTILITY INSTALLATION

Copy the TrendCom utility from the TrendCom CD (not included) onto a PC running MS-Windows.

### TRENDCOM UTILITY OPERATION

**NOTE:** Ensure the appropriate USB-Serial software driver is installed on the PC, if using a USB-Serial cable. PC must have Excel® spreadsheet software, or another program capable of using a .csv (comma separated value) file to view trend information. Information can be viewed as a .txt file. Trend information data is limited by the instrument's parameters.

#### Download Trend Data from Radical-7

##### A) Attach the USB-Serial or Serial-Serial Cable

**NOTE:** The Radical-7 handheld must be attached to a docking station. If using a USB-Serial cable, connect the serial cable from the RS-232 serial port on the back of the docking station to a USB port on the PC. If using a Serial-Serial cable, connect the cable from the RS-232 serial port on the back of the docking station to a serial port on the PC.

1. Press firmly to ensure the cable is fully engaged to the instrument.

##### B) Identify Correct COM Port

1. In the PC's Windows operating system, go to "Settings", then "Control Panel" and click on "System".
2. Click on the "Hardware" tab, then click on "Device Manager."
3. Find "Ports". Click on the plus (+) sign next to "Ports" and find either "USB Serial Port" (USB-Serial) or "Communications Port" (Serial-Serial). To the right of the Port name is the COM (Communications) Port ID #. Note the ID number.

##### C. Start the TrendCom Utility and Initiate Download

1. Assure that the Radical-7 Serial Output mode is set to "ASCII 2".
2. Open the Trendcom Software on the PC.
3. Under the "Instrument" menu in Trendcom, select "Radical-7", choosing the appropriate software level from the list.

NOTE: TrendCom will display "Invalid Data" message if the incorrect instrument is selected.

4. Under the "COM Port" menu, select the appropriate COM Port (ID number from Step B).
5. Click on "Retrieve Trend"





NOTE: The following message may appear: "Please make sure the Radical is set to ASCII 2 Output mode". If necessary, reset the Serial Output mode to "ASCII 2".

6. Name the file.
7. Save the file to the appropriate folder. Radical-7 trend information will consist of Date, Time, SpO2, Pulse Rate and Perfusion Index. Trend information will include Pleth Variability Index, SpCO, SpMet and/or SpHb, if the parameters are installed.

#### D) Disconnecting the Cable

1. Disconnect the USB-Serial or Serial-Serial cable from the instrument and PC. (See the specific cable's Directions for Use for instructions on attaching the patient cable to the instrument.)

#### ERASING TREND MEMORY

1. Ensure that the Radical-7 is in the Traditional User Interface.
2. Press  to access the trend menu.
3. Press  to enter the Trend menu.
4. Press  two (2) times to access the "Clear Trend" button.
5. Press  to delete Radical-7 trend data.

The Radical-7 continuously trends data. When performing a new study and gathering data on a new patient, it is highly recommended the "clear function" be utilized in order for the results to be separate. *Turning the Radical-7 off will not erase the trend data.*

#### TREND DATA FORMAT

After a successful download of the trend data, a .out file will be created containing the trend-dump information in ASCII delimited format. The format is defined in the following table.

PARAMETER	SPECIFICATION
Date	MM/DD\YY
Time	HH:MM:SS
Installed Parameter/ Measurement	Numeric value (see the display ranges in the Factory and User Configurable Default Settings table located at the beginning of this section)
Exception Messages	<p>The exceptions are displayed as a 3 digit, ASCII encoded, hexadecimal value. The binary bits of the hexadecimal value are encoded as follows:</p> <p>000 = Normal operation; no exceptions            001 = No Sensor            002 = Defective Sensor            004 = Low Perfusion            008 = Pulse Search            010 = Interference            020 = Sensor Off            040 = Ambient Light            080 = Unrecognized Sensor            100 = reserved            200 = reserved            400 = Low Signal IQ            800 = Masimo SET. This flag means the algorithm is running in full SET mode. It requires a SET sensor and needs to acquire some clean data for this flag to be set</p>



## SAMPLE TREND OUTPUT

```
07/21/08 09:56:08 SpO2=000 PR=000 PI=00.00 EXC=820:OffPat,SET
07/21/08 09:56:10 SpO2=000 PR=000 PI=00.00 EXC=828:Search,OffPat,SET
07/21/08 09:56:12 SpO2=097 PR=069 PI=04.69 EXC=800:SET
07/21/08 09:56:14 SpO2=096 PR=074 PI=02.28 EXC=C00:LowSigIQ,SET
07/21/08 09:56:16 SpO2=098 PR=078 PI=03.64 EXC=800:SET
07/21/08 09:56:18 SpO2=000 PR=000 PI=00.00 EXC=800:SET
07/21/08 09:56:20 SpO2=000 PR=000 PI=00.00 EXC=820:OffPat,SET
07/21/08 09:56:22 SpO2=096 PR=078 PI=02.68 EXC=800:SET
```

## Backlight Operation

The backlit LCD screen of the Radical-7 Pulse CO-Oximeter Handheld can be set to five levels of illumination when the Radical-7 Pulse CO-Oximeter operates as a standalone Pulse CO-Oximeter. The Radical-7 Pulse CO-Oximeter temporarily indicates the illumination level on the display following a change in illumination level. To select the level of illumination, simply press the Backlight button located on the front panel of the Handheld.

When the Radical-7 Pulse CO-Oximeter Handheld instrument is released from the Docking Station, the illumination of the LCD screen automatically reverts to the lowest level to conserve battery power. To select a different level of illumination, press the Backlight button again. In the Handheld mode, four levels of illumination are available.

When the Handheld instrument is re-attached to the Docking Station, as well as when the Radical-7 Pulse CO-Oximeter is powered on in the Standalone configuration, the backlight is automatically set to the maximum illumination when the instrument is AC line powered.

## SatShare Operation

When the SatShare cable is connected to the Radical-7 Pulse CO-Oximeter and to a multiparameter patient monitor, the Radical-7 Pulse CO-Oximeter automatically starts to operate in the SatShare mode.

In the SatShare mode, Radical-7 Pulse CO-Oximeter operates as follows:

- All visual alarms remain active.
- All audible alarms may be disabled by software configuration of the Radical-7 Pulse CO-Oximeter. Refer to Section 4, *Alarms*.
- The SpO<sub>2</sub> and pulse rate numbers may or may not be displayed on the Radical-7 Pulse CO-Oximeter display depending on the SatShare Numbers setting of the General menu. Refer to Section 3, *SatShare Setup*.
- All other items are displayed, including the alarm limits, the plethysmogram and Signal IQ waveform.
- The user can access the menu system.
- If the SatShare cable is connected to the Radical-7 Pulse CO-Oximeter only, and not to a patient monitor, the SatShare cable type is flashing on the LCD screen.
- Once the Radical-7 Pulse CO-Oximeter detects the presence of a patient monitor, the SatShare cable type remains constantly displayed on the LCD screen.
- Patient Alarms of the multiparameter patient monitor will be triggered by the alarm setting of the patient monitor and not the Radical-7 Pulse CO-Oximeter. To synchronize the alarm events set the alarm limits of the Radical-7 Pulse CO-Oximeter to those of the patient monitor, or vice versa.
- Once the Radical-7 Pulse CO-Oximeter detects that the SatShare cable is disconnected from the patient monitor, or if the patient monitor is turned off, the Radical-7 automatically returns to normal, standalone operation.
- In the SatShare mode, the pulse beep tone of the Radical-7 Pulse CO-Oximeter is initially set to the lowest volume (mute). The pulse beep volume can be manually increased. Refer to Section 4, *Traditional User Interface*.
- The Radical-7 Pulse CO-Oximeter may automatically set the averaging time during SatShare operation. For averaging times of 10 seconds and higher, the Radical-7 Pulse CO-Oximeter will automatically set the averaging time to 8 seconds during SatShare operation. Averaging times of 2, 4 or 8 seconds remain unchanged during SatShare operation. When the Radical-7 Pulse CO-Oximeter returns to non-SatShare operation, the Radical-7 Pulse CO-Oximeter will maintain the averaging time setting used in the SatShare mode.
- When the Radical-7 Pulse CO-Oximeter starts to operate in the SatShare mode the sensitivity mode is set to Normal sensitivity. The sensitivity mode can manually be set to Maximum or APOD sensitivity. Refer to Section 2, *Handheld Front Panel*.
- While operating in the SatShare mode, the Radical-7 Pulse CO-Oximeter may automatically disable the SatShare interface if the perfusion index drops below 0.1% while the sensitivity is set to Max sensitivity. To enable the SatShare interface again, set the Radical-7 Pulse CO-Oximeter to the Normal or APOD sensitivity mode, increase the perfusion at the measurement site (by warming the patient or sensor site), or move the sensor to a site with better perfusion.

## SatShare Operation (continued)

### CAUTIONS:

- SATSHARE SIGNALS ARE IDEAL SIMULATED WAVEFORMS CORRESPONDING TO THE CALCULATED SATURATION AND PULSE RATE VALUES AND DO NOT CONTAIN ALL OF THE INFORMATION CONTAINED IN PHYSIOLOGICAL WAVEFORMS. THE MULTIPARAMETER PATIENT MONITOR DECODES THESE SIGNALS INTO SATURATION AND PULSE RATE VALUES.
- DURING SATSHARE OPERATION, THE AUDIBLE ALARMS MAY BE MUTED ON THE RADICAL-7 PULSE CO-OXIMETER. WHEN THE AUDIBLE ALARM IS MUTED (INDICATED BY A BELL WITH A SLASH THROUGH IT) ON THE RADICAL-7 PULSE CO-OXIMETER, USE THE MULTIPARAMETER MONITOR FOR AUDIBLE ALARM INDICATION.
- THE (RADICAL-7) SpO<sub>2</sub> AND PULSE RATE AUDIBLE ALARMS MAY BE DISABLED WHEN THE RADICAL-7 IS CONFIGURED WITH RAINBOW PARAMETERS/ MEASUREMENTS. REFER TO SECTION 4, ALARMS.
- THE RADICAL-7 REVERTS TO THE INTERFACE ALARM SpO<sub>2</sub>/BPM “Yes” SETTING DURING POWER INTERRUPTIONS OR WHEN THE SATSHARE CONNECTION IS LOST OR THE Instrument BECOMES SEPARATED FROM THE DOCKING STATION. THIS ENSURES THAT THE RADICAL-7 PROVIDES AUDIBLE ALARMS FOR SpO<sub>2</sub> AND PULSE RATE WHEN THE CONNECTION TO THE INTERFACED SYSTEM BECOMES COMPROMISED.
- DURING SATSHARE OPERATION DO NOT USE THE PLETHYSMOGRAPHIC WAVEFORM DISPLAY ON THE MULTIPARAMETER MONITOR FOR DIAGNOSTIC PURPOSES. INSTEAD, USE THE PLETHYSMOGRAPHIC WAVEFORM DISPLAYED ON THE RADICAL-7 SCREEN.
- TO AVOID EXCESSIVE BATTERY DISCHARGING, DO NOT CONNECT ANY EQUIPMENT TO THE SATSHARE CONNECTOR UNLESS THE RADICAL-7 IS CONNECTED TO THE AC MAINS POWER SUPPLY.
- ONLY USE A SATSHARE CABLE THAT HAS A FERRITE BEAD INSTALLED.
- ONLY SPO<sub>2</sub> AND PULSE RATE CAN BE DISPLAYED ON THE MULTIPARAMETER MONITOR WITH SATSHARE.

To return from SatShare operation to normal standalone operation, simply disconnect the SatShare cable from the patient monitor or disconnect the SatShare cable from the SatShare connector on the back of the Radical-7 Pulse CO-Oximeter.

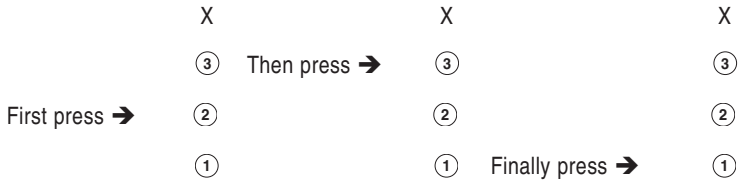
## Home Mode Operation

The Radical-7 Pulse CO-Oximeter can be placed into the Home Mode to protect unqualified users from changing the Radical-7 Pulse CO-Oximeter alarm settings and operation. Entering a password does not automatically reset the Radical-7 Pulse CO-Oximeter to the Normal operating mode. In the Home Mode, a password is required to access the menu system and the touch key control buttons and icons.

**NOTE:** When the Radical-7 Pulse CO-Oximeter is set to operate in the Home mode the default values that the Radical-7 reverts to after a power cycle are set according to Section 3, Monitor Setup, with the exception of the Alarm Silence setting, which is set to the pre-power down setting.

## Password Operation

The Radical-7 Pulse CO-Oximeter password is 2-3-1. To enter the password use the touch-key control buttons to the right or bottom of the LCD display and press the buttons in the sequence shown in the following figure:



## Alarm Identification

The Radical-7 visually and audibly indicates alarm conditions that the system detects. Audible alarms may be silenced, without affecting the operation of visual alarms.

Three levels of alarm priority are implemented: high, medium and low priority. The following table outlines the alarm priority specifications.

ALARM PRIORITY	PARAMETER/MEASUREMENT — ALARM SETTING RANGE	ALARM TYPE
High	Low arterial oxygen saturation	Audible and visual
	High carboxyhemoglobin saturation	
	High methemoglobin saturation	
	Low total hemoglobin High total hemoglobin	
	Low pulse rate High pulse rate	
	Sensor off and no sensor	
	Defective Sensor	
	Defective patient cable	
	System failures	
Medium	3D ALARM	Audible and visual
	Low battery, monitoring patient	Audible
Low	High saturation	Audible and visual
	Low PI High PI	
	Low PVI High PVI	
	Low carboxyhemoglobin saturation Low methemoglobin saturation	
	Low battery, not monitoring patient	

**NOTE:** There are no alarms associated with SpOC.

## System Messages

The following chart alphabetically lists all system messages displayed on the LCD screen. The cause of the message, and the action(s) to be taken are also shown.

The operator should become thoroughly familiar with this information before using the Pulse CO-Oximeter for patient monitoring.

MESSAGE	POSSIBLE CAUSE(S)	RECOMMENDATION
<b>REPLACE SENSOR</b>	SpHb reusable sensor has used all its available monitoring time.  Sensor is non-functional.	Replace sensor.
<b>DEFECTIVE CABLE</b>	Pulse CO-Oximeter cannot identify the connected cable or the cable has failed.	Inoperative or faulty cable; Replace cable. Refer to the Directions for Use of the cable being used.
<b>REPLACE SENSOR</b>	Defective sensor.	Replace sensor.
<b>INCOMPATIBLE SENSOR</b>	Not a proper Masimo sensor.	Replace with a proper Masimo sensor. Refer to Section 8.
	SpHb sensor is attached to a instrument without SpHb installed.	Use a non-SpHb sensor.  Contact your local Masimo Representative to learn more about the optional SpHb upgrade.
<b>INVALID SENSOR</b>	Not a compatible Masimo sensor.	Replace with a proper Masimo sensor. Refer to Section 8.
	SpHb sensor is attached to a instrument without SpHb installed.	Use a non-SpHb sensor.  Contact your local Masimo Representative to learn more about the optional SpHb upgrade.
<b>NO ADHESIVE</b>	When a single patient use sensor is used, the adhesive portion of the sensor is not connected. (Applies to Rainbow ReSposable CO-Oximeter Sensor Systems, or ReSposable Pulse CO-Oximeter Sensor Systems only.)	Ensure the adhesive portion is firmly connected to the sensor.
<b>INVALID ADHESIVE</b>	When a single patient use sensor is used, the adhesive portion of the sensor is incompatible or unrecognized. (Applies to Rainbow ReSposable CO-Oximeter Sensor Systems, or ReSposable Pulse CO-Oximeter Sensor Systems only.)	Connect the correct adhesive portion of the sensor.

MESSAGE	POSSIBLE CAUSE(S)	RECOMMENDATION
<b>REPLACE ADHESIVE</b>	When a single patient use sensor is used, the adhesive portion of the sensor is non-functional, or the life of the adhesive portion of the sensor has expired. (Applies to Rainbow ReSposable CO-Oximeter Sensor Systems, or ReSposable Pulse Oximeter Sensor Systems only.)	Replace the adhesive portion of the sensor.
<b>REPLACE REUSABLE</b>	The reusable sensor (i.e., the durable portion that includes the emitter and detector) is non-functional, or the life of the reusable sensor has expired. (Applies to Rainbow ReSposable CO-Oximeter Sensor Systems, or ReSposable Pulse Oximeter Sensor Systems only).	Replace the reusable sensor.
<b>REPLACE CABLE</b>	The patient cable is non-functional, or the life of the cable has expired.	Replace the patient cable.
<b>INTERFERENCE</b>	High intensity light such as pulsating strobe lights, excessive ambient light sources such as surgical lights or direct sunlight, or other monitor displays.	Place a Masimo Optical Light Shield over the sensor.
	Incorrect monitor line frequency setting (Hz).	Access the Traditional User Interface described in Section 4. Select Config and enter the password. Adjust the Line Frequency to the correct Hz setting.
<b>CHECK SENSOR</b>	Sensor is not connected firmly into patient cable, or the sensor is not connected firmly to the instrument.	Reconnect sensor firmly into patient cable, or to the instrument.
<b>SPO2 ONLY MODE</b>	"SpO2 Only Mode" message occurs during an unsuccessful sensor calibration/pulse search routine, or during monitoring.	Review the sensor's Directions for Use instructions, Section 4, Successful Monitoring, and Section 8, Selecting a Masimo SET Sensor.
<b>LOW BATTERY</b>	Battery charge is low.	Charge battery by placing the Radical-7 Handheld into the Docking Station and powering the instrument with AC line power. Replace battery if necessary.
<b>LOW PERFUSION</b>	Signal too small.	Move sensor to better perfused site. Refer to Section 4, Low Perfusion.

MESSAGE	POSSIBLE CAUSE(S)	RECOMMENDATION
<b>LOW SIGNAL IQ</b>	Low signal quality.	Ensure proper sensor application. Move sensor to a better perfused site. Refer to Section 4, Signal IQ.
<b>LOW SpCO SIQ</b>	SpCO measurement reading is obscured.	Ensure proper sensor application. Check sensor to see if it is working properly. If not, replace the sensor. Refer to Section 4, Numeric Display - SpCO.
<b>LOW SpMet SIQ</b>	SpMet measurement reading is obscured.	Ensure proper sensor application. Check sensor to see if it is working properly. If not, replace the sensor. Refer to Section 4, Numeric Display - SpMet.
<b>LOW SpHb SIQ</b>	SpHb measurement reading is obscured.	Ensure proper sensor application. Check sensor to see if it is working properly. If not, replace the sensor. Refer to Section 4, Numeric Display - SpHb.
<b>SPEAKER FAILURE</b>	Instrument requires service.	Contact Masimo Tech Support. Refer to Section 9, <i>Service and Repair</i> .
<b>NO CABLE</b>	Cable not attached or not fully inserted into the connector.	Disconnect and reconnect cable into connector.
<b>NO SENSOR</b>	Sensor not fully inserted into the connector.	May be an incorrect sensor, or a defective sensor or cable. Insert sensor into connector. Disconnect and reconnect sensor. Refer to the instructions for the sensor being used.
	Instrument is searching for patient's pulse.	Disconnect and reconnect the sensor into the Patient Cable Connector.
<b>PULSE SEARCH</b>	Instrument is searching for patient's pulse.	If values are not displayed within 30 seconds, disconnect and reconnect sensor. If pulse search continues, remove sensor and replace on a better perfused site.
<b>SENSOR CALIBRATING</b>	Instrument is checking the sensor for proper functioning and performance.	If values are not displayed within 30 seconds, disconnect and reconnect sensor. If values are still not displayed, replace with a new sensor.
<b>SENSOR OFF</b>	Sensor off patient.	Disconnect and reconnect sensor. Reattach sensor.
<b>SERVICE REQUIRED*</b>	Internal Failure.	Instrument requires service.
<b>UNRECOGNIZED CABLE</b>	Not a proper cable.	Replace with a proper cable. Refer to Section 8.

\*The SERVICE REQUIRED message fills the entire display. This is a numeric error code. Contact Masimo for service.



## 3D ALARM Overview

The Radical-7 Pulse CO-Oximeter includes user-selectable High and Low alarm limits for SpO<sub>2</sub> and pulse rate to provide audible and visual indication of specific levels of these vital signs that the clinician has determined merits their attention as described in Section 5 of this manual. The 3D ALARM enables clinicians to be alerted to changes in multiple interacting factors to provide an additional level of vigilance and flexibility to manage their patients.

The following is a summary of each of the 3D ALARM features:

### DESAT INDEX ALARM

The Desat Index Alarm is a user-selectable feature which allows a clinician to request an audible and visual alarm if a patient experiences a specified number of desaturations over a specific period of time.

### PERFUSION INDEX (PI) DELTA ALARM

The PI Delta Alarm is a user-selectable feature which allows a clinician to request an audible and visual alarm if perfusion at the monitored site decreases by a specified level (delta) over a specific period of time.

**NOTE:** *The alarms in this system are considered to be Medium priority.*

## Desat Index Alarm

Traditional high and low SpO<sub>2</sub> alarm limits alert clinicians to saturation levels that exceed user-selected thresholds, and these thresholds are typically established at a considerable change from the patients' baseline saturation level. However, in select patient populations, substantial desaturation events that exceed a typical low alarm limit threshold may be preceded by a cycle of transient desaturations over a limited timeframe, and the ability to alert clinicians to a cycle of these smaller desaturations may provide an earlier indication of a potential significant decline in the patient's status and the need for more focused monitoring and/or a change in treatment.

To address patient populations at risk for cyclic, moderate desaturations, the 3D ALARM option includes a user-selectable Desat Index Alarm which allows the clinician to request an audible and visual alarm in the event the patient experiences a specified number of desaturations beyond a defined level from the patient's baseline saturation over a specific window of time, with each of these variables selectable by the user within established ranges as noted below:

Desat Index Threshold:	Range of 2% to 10% in 1% increments, default of 4%
Desat Index Timeframe:	Range of 1 to 4 Hrs in 1-Hr increments, default of 1 Hr
Desat Index Alarm/Quantity:	Range of 1 to 25 desaturations, default is OFF

To translate the above Desat Index variables and ranges into perspective, consider a patient at risk of respiratory compromise with the definition for respiratory compromise of 5 or more transient moderate desaturations (associated with a 4% drop in SpO<sub>2</sub>) per hour. To request a Desat Index alarm for this situation, the clinician would set the Desat Index variables as follows:

Desat Index Threshold:	4%
Desat Index Timeframe:	1 hour
Desat Index Alarm	5 (desaturations)

Post-operative patients receiving pain medication may be predisposed to respiratory depression. If the patient has an underlying respiratory condition, pain medication may cause the patient to spiral into a cascade of cyclic desaturations, which initially are mild but may worsen quickly. The Desat Index Alarm may give an early warning of this type of respiratory disturbance that can lead to respiratory depression and even arrest.

**CAUTION:** THE DESAT INDEX ALARM IS INTENDED AS AN ADJUNCT RATHER THAN IN PLACE OF THE LOW SATURATION ALARM.

## USER INTERACTION TO IMPLEMENT DESAT INDEX ALARM

The Desat Index Alarm function is enabled in the Radical-7 by the following method:

1. Select the 3D ALARM menu from the main menu page.
2. Select Desat Index.
3. The Desat Index Alarm menu will be displayed and the user can select from the following entries:

Desat Index Threshold:	Range of 2% to 10% in 1% increments, default of 4%
Desat Index Time:	Range of 1 Hr to 4 Hrs in 1-HR increments, default of 1 Hr
Desat Index Alarm:	Range of 1 to 25 desaturations, default is OFF

If the measured Desat Index parameter is greater than the configured Desat Index Alarm level selected, the Radical-7 will make a MEDIUM priority alarm tone and post an alarm message as follows:

$$\text{DESAT INDEX} = \#\#$$

where ## is equal to the current Desat Index and updates real time.

If the Alarm Silence key is pressed during the Desat Index alarm, the tone is silenced and will not return when the Alarm Suspend time expires unless the condition is removed and then returns. The message will remain on the screen until the Alarm condition is removed.

## Perfusion Index (PI) Delta Alarm

Perfusion Index gives an indication of the level of perfusion at the monitored site. The Radical-7 measures perfusion at the SpO<sub>2</sub> site by comparing the pulsatile signal to the non-pulsatile signal, and expressing that ratio as a percentage. PI has been clinically proven to be useful as a predictor of the level of illness in neonates and adults and that PI may change dramatically in response to sympathetic changes caused by inhalational agents and pain stimulation<sup>4</sup>. If PI decreases over time, there may be underlying physiological reasons that may need to be addressed.

<sup>4</sup> De Felice C, Latini G, Vacca P, Kopotic RJ. The pulse oximeter perfusion index as a predictor for high illness severity in neonates. Eur J Pediatr. 2002;161:561-562.

The 3D ALARM provides an audible and visual alert to important changes in perfusion compared to the patient's baseline PI rate. The baseline is set by the Radical-7 once the user has enabled the alarm. The baseline is 30 seconds of currently averaged PI. The 3D ALARM includes a user-selectable PI Delta Alarm. This allows the clinician to request an audible and visual alarm if perfusion at the monitored site decreases by a specified level (delta) over a specified window of time. Three of the variables are selectable by the user within established ranges as noted below:

Set Baseline:	Select OFF or SET. Default is OFF.
PI Delta % Change:	Range of 10% to 100%. Default is 50%.
PI Delta Timeout	Range of 1 min, 5 min, 30 min, 1 hr. 4 hr, 8 hr, 12 hr, 24 hr, 36 hr, 48 hr and NONE. Default is NONE.
PI Delta Baseline	Displays OFF, the current PI baseline or TIMEOUT. <b>NOTE:</b> This is a Read Only display and not user interactive.

### USER INTERACTION TO IMPLEMENT PI DELTA ALARM

The PI Delta Alarm function is enabled in the Radical-7 by the following method:

1. Select the 3D ALARM menu from the main menu page.
2. Select PI Delta.
3. The PI Delta Alarm menu will be displayed and the user can select from the following entries:

Set Baseline:	Select OFF or SET. Default is OFF.
PI Delta % Change:	Range of 10% to 100%. Default is 50%.
PI Delta Timeout	Range of 1 min, 5 min, 30 min, 1 hr. 4 hr, 8 hr, 12 hr, 24 hr, 36 hr, 48 hr and NONE. Default is NONE.
PI Delta Baseline	Displays OFF, the current PI baseline or TIMEOUT. <b>NOTE:</b> This is a Read Only display and not user interactive.

## USER INTERACTION TO IMPLEMENT PI DELTA ALARM (CONTINUED)

If the PI Delta measurement is greater (more negative) than the configured PI Delta Alarm, then the Radical-7 will make a MEDIUM priority alarm tone, and post an alarm message as follows:

$$\text{PI DELTA} = \#\\%$$

where ## is equal to the current PI Delta percentage and updates real time.

The PI trend graph will also display.

If the Alarm Silence key is pressed during this alarm, the tone shall be silenced and not returned when the Alarm Suspend time expires unless the condition is removed and then returns. The message will remain on the screen until the Alarm condition is removed.

## 3D ALARM menu

PARAMETER	MENU ITEM	DESCRIPTION
DESAT INDEX ALARM	DESAT THRESH-OLD	The Desat Threshold can be set in the range of 2% to 10% in 1% increments. Default is 4%.
	DESAT INDEX TIME	The Desat Index Time can be set in the range of 1 Hr to 4 Hrs in 1-Hr increments. Default is 1 hr.
	DESAT INDEX ALARM	The Desat Index Alarm can be set in the range of 1 to 25 desaturations. Default is OFF.
PI DELTA ALARM	SET BASELINE	The Set Baseline can be turned on by selecting SET. Selecting OFF disables the alarm. Default is OFF.
	PI DELTA % CHANGE	The PI Delta % Change can be set in the range of 10% to 100%. Default is 50%.
	PI DELTA TIMEOUT	The PI Delta Timeout can be set in the range of the following increments: 1 min, 5 min, 30 min, 1 hr, 4 hr, 8 hr, 12 hr, 24 hr, 36 hr, 48 hr and NONE. Default is NONE.
	PI DELTA BASE-LINE	The PI Delta Baseline displays OFF, the current PI baseline or TIMEOUT. <b>NOTE:</b> This is a Read Only display and not user interactive.



## Troubleshooting

The following chart describes what to do if the Radical-7 Pulse CO-Oximeter system does not operate properly or fails.

PROBLEM	POSSIBLE CAUSE(S)	RECOMMENDATION
<b>INSTRUMENT DOES NOT POWER ON</b>	One or both of the fuses are not operating properly.	Replace the fuses.
<b>INSTRUMENT POWERS ON BUT THE GRAPHIC DISPLAY IS BLANK</b>	The viewing contrast is not correct.	Use the Backlight/Contrast button to adjust the viewing angle. If the condition persists, the instrument requires service.
<b>CONTINUOUS SPEAKER TONE</b>	Internal failure.	Instrument requires service. Press the Alarm Silence button to silence the alarm. If alarm continues to sound, power down instrument and remove Handheld battery if necessary.
<b>BUTTONS DON'T WORK WHEN PRESSED</b>	Internal failure.	Instrument requires service.
<b>DEFECTIVE SENSOR MESSAGE</b>	Sensor or cable is broken.	Visually check the sensor LED if it is flashing on and off. If not, reconnect the cable and check the LED again. If the LED still fails to come on, replace the sensor and/or cable.

The following chart describes what to do when encountering common problems.

PROBLEM	POSSIBLE CAUSE(S)	RECOMMENDATION
<b>SpO<sub>2</sub> NUMBER FLASHES</b>	Saturation alarm limit exceeded.	Assess/address patient condition. Reset alarm limits if indicated.
<b>SENSOR OFF MESSAGE</b>	Sensor not connected to patient properly. Sensor is damaged.	Properly reapply the sensor on the patient and reconnect the sensor to the instrument or patient cable. If the sensor is damaged, replace the sensor.
<b>NO SENSOR MESSAGE</b>	Sensor is disconnected from patient cable. Sensor connected upside down into patient cable.	Check to see if the sensor LED is flashing. Disconnect and reconnect the sensor. If the LED fails to operate, replace the sensor.
<b>LOW PERFUSION</b>	Improper sensor type. Poorly perfused site. Sensor is too tight. A disorder such as hypothermia, vasoconstriction, hypovolemia, peripheral vascular disease or anemia. Sensor is damaged.	Verify proper sensor and sensor size for the patient. Check and see if blood flow to the site is restricted. Be sure that the sensor is not on too tight. Set instrument to MAX sensitivity. Warm the patient or sensor site. Move sensor to better perfused site.

## Troubleshooting (continued)

PROBLEM	POSSIBLE CAUSE(S)	RECOMMENDATION
<b>LOW SIGNAL QUALITY</b>	Improper sensor type or application. Excessive motion relative to perfusion. Sensor is damaged or not functioning.	Check and see if blood flow to the site is restricted. Check the placement of the sensor. Re-apply sensor or move to a different site.
<b>SpO<sub>2</sub> VALUES DO NOT CORRELATE WITH CLINICAL ASSESSMENT OR ABGs</b>	Low perfusion or sensor displacement.	Check for error messages. See section 5 <i>System Messages</i> for recommended corrections. Check placement of sensor or if it is too tight. Reapply sensor or select a new site. Set to MAX sensitivity and confirm that the sensor is securely on the patient. Refer to sensor Directions For Use.
<b>PULSE SEARCH MESSAGE</b>	Instrument is searching for pulse.	If instrument fails to display within 30 seconds, disconnect and reconnect. If pulse search continues, move sensor to better perfused site.
<b>UNEXPECTED SpO<sub>2</sub>, SpCO, SpMet OR SpHb READING</b>	Low SIQ or Perfusion Index (PI) values.	Reposition sensor to site with strong SIQ and PI. Average readings taken from three different sites to improve accuracy. Submit blood sample for laboratory CO-Oximetry test for comparison.
	Inappropriate sensor size or sensor measurement location.	Verify proper sensor for patient size. Verify proper sensor site.
<b>UNEXPECTEDLY HIGH SpCO READING</b>	Possible elevated methemoglobin level.	Submit blood sample for laboratory CO-Oximetry test.
<b>DIFFICULTY OR NO SpCO/SpMet/SpHb READING</b>	Low battery/ not plugged into AC power supply.	Insert handheld into docking station, verify docking station power cord plugged in and docking station power indicator light is illuminated.
	Interference from line-frequency induced noise.	Verify/set 50/60hz menu setting. Refer to Section 3, <i>Initial Setup</i> for details.
	Inappropriate sensor or sensor size.	Verify proper sensor and sensor size for the patient.
	Excessive ambient or strobing light.	Shield the sensor from excessive or strobing light.
	Excessive motion.	Minimize or eliminate motion at the monitoring site.
	Also, see Section 4, <i>Successful Monitoring</i> for additional information.	
<b>HANDHELD BATTERY DOES NOT CHARGE</b>	AC power cable may be disconnected.	Restore power to the instrument.



## Troubleshooting (continued)

PROBLEM	POSSIBLE CAUSE(S)	RECOMMENDATION
PRINT FUNCTION DOES NOT WORK	Wrong serial cable is used	Make sure a null modem cable is used.
LED LIGHTS ON LEFT SIDE OF DOCKING STATION CONTINUOUSLY FLASH	Incompatible version of software on Radical-7 handheld and docking station.	Upgrade to current software versions. Match handheld to docking station with compatible software versions
BATTERY RUN-TIME IS SIGNIFICANTLY REDUCED	Battery Memory effects.	Use Battery Discharge function as described in Section 4, <i>Service</i> .



## Radical-7 Specifications

### PERFORMANCE

#### Measurement Range

SpO <sub>2</sub> :	0 - 100%
SpMet:	0 - 99.9%
SpCO:	0 - 99%
SpHb	0 - 25 g/dl
SpOC	0 - 35 ml of O <sub>2</sub> /dl of blood
Pulse Rate:	25 - 240 (bpm)
Perfusion Index:	0.02% - 20%
Pleth Variability Index:	0 - 100%

### ACCURACY

#### Oxygen Saturation Accuracy<sup>1</sup>

Saturation	60% to 80%
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#### No Motion

Adults, Infants, Pediatrics	± 3%
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Saturation	70% to 100%
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#### No Motion<sup>2</sup>

Adults, Infants, Pediatrics	± 2%
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Neonates	± 3%
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#### Motion<sup>3</sup>

Adults, Infants, Pediatrics, Neonates	± 3%
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#### Low Perfusion<sup>4</sup>

Adults, Infants, Pediatrics, Neonates	± 2%
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#### Pulse Rate Accuracy<sup>5</sup>

Pulse rate:	25 - 240 bpm
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#### No Motion

Adults, Infants, Pediatrics, Neonates	± 3 bpm
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#### Motion<sup>4</sup>

Adults, Infants, Pediatrics, Neonates	± 5 bpm
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#### Low Perfusion

Adults, Infants, Pediatrics, Neonates	± 3 bpm
---------------------------------------	---------

#### Carboxyhemoglobin saturation accuracy (%SpCO)<sup>1</sup>

Adults, Infants, Pediatrics	1% - 40% ± 3%
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#### Methemoglobin saturation accuracy (%SpMet)<sup>1</sup>

Adults, Infants, Pediatrics, Neonates	1% - 15% ± 1%
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#### Total Hemoglobin accuracy (SpHb g/dl)<sup>6</sup>

Adults, Pediatrics	8 - 17 g/dl ± 1 g/dL
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#### Resolution

Oxygen Saturation (%SpO <sub>2</sub> )	1%
Carboxyhemoglobin Saturation (%SpCO)	1%
Methemoglobin Saturation (%SpMet)	0.1%
Total Hemoglobin (SpHb g/dl)	0.1 g/dl
Pulse Rate (bpm)	1 bpm

## Radical-7 Specifications (continued)

### ELECTRICAL

#### Standalone

AC Power requirements:	100-240 VAC, 47-63 Hz
Power consumption:	55 VA
Fuses:	1 Amp, Fast Acting, Metric, (5x20mm), 250V

#### Batteries

##### Handheld:

Type:	NiMH
Capacity:	4 hours <sup>7</sup>
Charging time:	3 hours

##### Docking Station (RDS-1B):

Type:	NiMH
Capacity:	10 hours <sup>7</sup>
Charging time:	6 hours

### ENVIRONMENTAL

Operating Temperature:	41°F to 104°F (5°C to 40°C)
Transport/Storage Temperature:	-40°F to 158°F (-40°C to +70°C) <sup>8</sup>
Operating Humidity:	5% to 95%, non-condensing
Operating Altitude:	500 mbar to 1060 mbar pressure -1000 ft to 18,000 ft (-304 m to 5,486 m)

### PHYSICAL CHARACTERISTICS

#### Dimensions

Handheld:	8.9" x 3.5" x 2.1" (22.6 cm x 8.9cm x 5.3 cm)
Standalone:	3.5" x 10.5" x 7.7" (8.9 cm x 26.7cm x 19.6cm)

#### Weight

Handheld:	1.2 lbs. (0.54 kg)
Docking Station (RDS-1, RDS-2, RDS-3):	2.5 lbs. (1.14 kg)
Docking Station (RDS-1B):	4.11 lbs (1.86 kg)
Standalone (RDS-1, RDS-2, RDS-3):	3.8 lbs. (1.73 kg)
Standalone (RDS-1B):	5.4 lbs. (2.45 kg)

#### Trending

72 hours of trending at 2 second resolution, > 10 days of trending at 10 second resolution, output to serial printer or other serial instruments

#### Mode

Averaging mode:	2, 4, 8, 10, 12, 14 or 16 seconds <sup>9</sup>
Sensitivity:	Normal and Maximum <sup>10</sup> and APOD

#### Alarms

Audible and visual alarms for high/low saturation, pulse rate, SpCO, SpMet, SpHb, PI, PVI (SpO<sub>2</sub> range 1-99%, pulse rate range 30-235 bpm, SpCO 1-98%, SpMet .1-99.5%, SpHb 1-24.5 g/dl, PI .03-19%, PVI 1-99%)

## Radical-7 Specifications (continued)

Sensor condition, system failure and low battery alarms	
High Priority:	571 Hz tone, 5 pulse burst, pulse spacing: 0.250s, 0.250s, 0.500s, 0.250s, repeat time: 10s
Medium Priority:	550 Hz tone, 3 pulse burst, pulse spacing: 0.375s, 0.375s, repeat time: 7s
Low Priority:	500 Hz tone, 1 pulse burst, repeat time: 5s
Alarm Muted reminder:	500Hz tone, 2 pulse burst, pulse spacing 0.375s, repeat time: 3min.
Alarm Volume:	High Priority: 70 dB (min), Medium Priority: 70 dB (min), Low Priority: 45 dB (min)

### Display/Indicators

Data display:	%SpO <sub>2</sub> , %SpCO, %SpMet, SpHb g/dl, SpOC ml/dl, PVI, pulse rate, plethysmographic waveform, alarm status, trends, status messages, Signal IQ, perfusion index, APOD and FastSat
Display update rate:	1 second
Response Time:	< 20 second delay
Type:	Backlit Active Matrix TFT LCD
Pixels:	480 x 272 dots
Dot Pitch:	0.25 mm

### Output Interface

SatShare (RDS-1, RDS-1B)
Serial RS-232 (RDS-1, RDS-1B, RDS-3)
Nurse Call/Analog Output (RDS-1, RDS-1B, RDS-3)
Philips Vuelink, Spacelabs Universal Flexport, RadNet, Patient SafetyNet (RDS-1, RDS-1B, RDS-3)

### Compliance

EMC Compliance:	EN60601-1-2, Class B
Equipment Classification:	IEC 60601-1 / UL 60601-1
Type of Protection	Class 1 (on AC power), Internally powered (on battery power)
Degree of Protection-Patient Cable:	Type BF-Applied Part
Degree of Protection-SatShare Cable:	Type CF-Applied Part
Mode of Operation:	Continuous

- 1 SpO<sub>2</sub>, SpCO and SpMet accuracy was determined by testing on healthy adult volunteers in the range 60% - 100% SpO<sub>2</sub>, 0% - 40% SpCO and 0% - 15% SpMet against a laboratory CO-Oximeter. SpO<sub>2</sub> and SpMet accuracy was determined on 16 neonatal NICU patients ranging in age from 7 to 135 days old and weighting between 0.5 and 4.25 kgs. Seventy-nine (79) data samples were collected over a range of 70 - 100% SaO<sub>2</sub> and 0.5 - 2.5% HbMet with a resultant accuracy of 2.9% SpO<sub>2</sub> and 0.9% SpMet. Contact Masimo for testing specifications.
- 2 The Masimo Rainbow SET technology with Masimo sensors has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO<sub>2</sub> against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population weight.
- 3 The Masimo Rainbow SET technology with Masimo sensors has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO<sub>2</sub> against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

## Radical-7 Specifications (continued)

- 4 The Radical-7 has been validated for low perfusion accuracy in bench-top testing against a BioteK Index 2™\* simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70-100%. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
- 5 Masimo Rainbow SET technology with Masimo sensors has been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a BioteK Index 2 simulator. This variation equals plus or minus one standard deviation which encompasses 68% of the population.
- 6 SpHb accuracy has been validated on healthy adult male and female volunteers and on surgical patients with light to dark skin pigmentation in the range of 8 g/dL to 17 g/dL SpHb against a laboratory CO-Oximeter. The variation equals plus or minus one standard deviation which encompasses 68% of the population. The SpHb accuracy has not been validated with motion or low perfusion.
- 7 This represents approximate run time at the lowest indicator brightness and pulse tone turned off using a fully charged battery.
- 8 If the batteries are to be stored for extended periods of time, it is recommended that they be stored between -20°C to +30°C, and at a relative humidity less than 85%. If stored for a prolonged period at environmental conditions beyond these limits, overall battery capacity may be diminished, and lifetime of the batteries may be shortened.
- 9 With FastSat the averaging time is dependent on the input signal. For the 2 and 4 second settings the averaging time may range from 2-4 and 4-6 seconds, respectively.
- 10 Maximum sensitivity mode fixes perfusion limit to 0.02%.

\*Registered trademark of Fluke Biomedical Corporation, Everett, Washington.

## Serial Interface Specifications

The digital interface for serial communication is based on the standard RS-232 protocol.

The Radical-7 Pulse CO-Oximeter by default always outputs ASCII 1 text data through the serial port, unless the user selects a different output mode in the Output menu. To interface with the Radical-7 Pulse CO-Oximeter and receive serial text data, simply connect a serial interface cable with a ferrite bead installed to the serial output connector located on the back of the Radical-7 Docking Station.

**NOTE:** The Radical-7 Pulse CO-Oximeter serial interface is only available when the Radical-7 Pulse CO-Oximeter Handheld is properly attached to the Radical-7 Pulse CO-Oximeter Docking Station.

**NOTE:** The serial interface is not available in all versions of the docking station.

Once serial communication is established, packets of data are communicated at 1 second intervals. The data packets contain: the date, time, SpO<sub>2</sub>, SpMet, SpCO, SpHb, SpOC, pulse rate, perfusion index, PVI, and alarm and exception values (in ASCII format).

**WARNING:** ALL EXTERNAL INSTRUMENT CONNECTIONS TO THE ANALOG OUTPUT/ NURSE CALL CONNECTOR MUST BE IEC-60950 COMPLIANT.

## SERIAL INTERFACE SETUP

To interface with the Radical-7 Pulse CO-Oximeter serial port, set the following communication parameters on the interfacing serial instrument:

PARAMETER	SETTING
BAUD RATE	9600 Baud bi-directional
NUMBER OF BITS PER CHARACTER	8
PARITY	None
BITS	1 start, 1 stop
HANDSHAKING	None
CONNECTOR TYPE	Female DB-9

## SERIAL INTERFACE SETUP (CONTINUED)

The pin-outs for the RS-232 connector are shown in the following table:

PIN	SIGNAL NAME
1	No Connection
2	Receive data – RS-232 $\pm 9$ V ( $\pm 5$ Vmin)
3	Transmit data – RS-232 $\pm 9$ V ( $\pm 5$ Vmin)
4	No Connection
5	Signal Ground Reference for COM signals
6	No Connection
7	No Connection
8	No Connection
9	No Connection

## SERIAL PRINTER SETUP

To print the SpO<sub>2</sub> and pulse rate data in ASCII 1 format on a serial printer, simply connect the serial printer to the serial port. Once serial communication is established, the Radical-7 Pulse CO-Oximeter will automatically start printing the ASCII 1 text data.

**WARNING:** ALL EXTERNAL INSTRUMENT CONNECTIONS TO THE RS-232 SERIAL PORT MUST BE IEC-60950 COMPLIANT.

## Analog Output/Nurse Call Specifications

The Analog Out and Nurse Call are features accessible on the same female high density DB-15 connector.

**NOTE:** The Radical-7 Pulse CO-Oximeter analog output / nurse call interface is only available when the Radical-7 Pulse CO-Oximeter Handheld is properly attached to the Radical-7 Pulse CO-Oximeter Docking Station. Only use an analog / nurse call cable that has a ferrite bead installed.

**NOTE:** The analog output / nurse call interface is not available in all versions of the Docking Station.

The following table shows the pinout of the analog output and nurse call.

PIN	SIGNAL NAME
1	+5V (60mA max.)
2	Ground
3	Ground
4	Ground
5	Ground
6	Nurse Call (Normally Open)

PIN	SIGNAL NAME
7	Nurse Call (Normally Closed)
8	Ground
9	Analog 1
10	Ground
11	Ground
12	Nurse Call – Common
13	Ground
14	Ground
15	Analog 2

### ANALOG OUTPUT

The Radical-7 Pulse CO-Oximeter can interface with various analog recording instruments and/or strip chart recorders through its Analog Output connector located on the back of the Docking Station. Depending on the configuration of the Output menu, the following parameters are output continuously on the Analog 1 and Analog 2 channels:

- SpO<sub>2</sub>
- Pulse rate
- Plethysmographic waveform
- Signal IQ

The output signals vary from approximately 0 to 1 volt in a linear fashion.

**NOTE:** The actual Analog 1 and Analog 2 output voltage that are generated may not exactly range between 0.0V to 1.0V. A variance of  $\pm 40$  mV is acceptable.

### CALIBRATION

For measurement instrument calibration purposes, the analog output signals can be set to either 0 Volts or 1 Volt in the menu system under Output/Analog Output Mode. Calibrate your analog recording system to those levels before use.

### NURSE CALL

The nurse call feature is available when Radical-7 Pulse CO-Oximeter is operating in its standalone configuration. The nurse call feature on the Radical-7 Pulse CO-Oximeter is based on the relay closing or opening depending on alarm, Low Signal IQ events or both. For maximum flexibility, either normally open (pin 6) or normally closed (pin 7) signals are available. Only qualified personnel should connect one of these two signals and common (pin 12) to a hospital's nurse call system. During an alarm condition, or a Low Signal IQ event, depending on the configuration of the output menu, the normally open pin will be connected to the common pin and the normally closed will be disconnected. In addition, the nurse call polarity can be inverted to accommodate various nurse call station requirements.



The nurse call relays have the following electrical specifications per switch:

PARAMETER	SPECIFICATION
MAX VOLTAGE	100VDC or AC peak
MAX CURRENT	100mA

**WARNING:** THE NURSE CALL FEATURE IS DISABLED WHEN THE AUDIBLE ALARMS ARE SILENCED WHILE THE NURSE CALL SETTING IN THE OUTPUT MENU IS SET TO "ALARMS".



## Introduction

This section covers the use and cleaning of Masimo sensors and patient cables.

Before use of any sensor, carefully read the sensor's Directions for Use.

Use only Masimo sensors and cables with the Radical-7 Pulse CO-Oximeter. Other transducers, sensors and cables may affect the Radical-7 Pulse CO-Oximeter performance.

Tissue damage can be caused by incorrect application or use of a sensor, for example by wrapping the sensor too tightly. Inspect the sensor site as directed in the sensor Directions for Use to ensure skin integrity, correct positioning and adhesion of the sensor.

### CAUTIONS:

- DO NOT USE DAMAGED SENSORS OR PATIENT CABLES. DO NOT USE A SENSOR OR PATIENT CABLE WITH EXPOSED OPTICAL OR ELECTRICAL COMPONENTS.
- DO NOT IMMERSE THE SENSOR OR PATIENT CABLE IN WATER, SOLVENTS, OR CLEANING SOLUTIONS (THE SENSORS AND CONNECTORS ARE NOT WATERPROOF).
- UNLESS OTHERWISE SPECIFIED, DO NOT STERILIZE SENSORS OR PATIENT CABLES BY IRRADIATION, STEAM, AUTOCLAVE OR ETHYLENE OXIDE. SEE THE CLEANING INSTRUCTIONS IN THE DIRECTIONS FOR USE FOR REUSABLE MASIMO SENSORS.
- DO NOT ATTEMPT TO REPROCESS, RECONDITION OR RECYCLE ANY MASIMO SENSORS OR PATIENT CABLES AS THESE PROCESSES MAY DAMAGE THE ELECTRICAL COMPONENTS, POTENTIALLY LEADING TO PATIENT HARM.
- ALL SENSORS AND CABLES ARE DESIGNED FOR USE WITH SPECIFIC MONITORS. VERIFY THE COMPATIBILITY OF THE MONITOR, CABLE AND SENSOR BEFORE USE, OTHERWISE PATIENT INJURY CAN RESULT.
- TO AVOID DAMAGE TO THE CABLES, ALWAYS HOLD THE CABLE BY THE CONNECTOR RATHER THAN THE CABLE WHEN CONNECTING OR DISCONNECTING EITHER END.

## SELECTING A MASIMO SET SENSOR

When selecting a sensor, consider the patient's weight, the adequacy of perfusion, the available sensor sites, and the duration of monitoring. For more information refer to the following tables or contact your Sales Representative. Use only Masimo sensors and sensor cables. Select an appropriate sensor, apply it as directed, and observe all warnings and cautions presented in the **Directions for Use accompanying the sensor**. Monitor, cables and sensors must be compatible to ensure optimal performance. Incompatible components effect operation or data recovery.

High intensity extreme lights (such as pulsating strobe lights) directed on the CO-Oximeter sensors, may not allow the sensor to obtain measurements. Excessive ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight, as well as other monitor displays, can interfere with the performance of the sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with a Masimo Optical Light Shield. Failure to take this precaution in excessive ambient light conditions may result in inaccurate measurements.

## SENSOR APPLICATION INSTRUCTIONS

Unless indicated otherwise in the directions for use, reposition reusable sensors at least every 4 hours and for adhesive sensors inspect the site at least every 8 hours or sooner. If indicated by circulatory condition or skin integrity, reapply to a different monitoring site.

## Masimo Sensors

The following sensors are compatible for use with the Radical-7 Pulse CO-Oximeter.

**See the sensor directions for use for full sensor specifications, including accuracy.**

### MASIMO RAINBOW SENSORS

Masimo Rainbow sensors must be used for the Radical-7 Pulse CO-Oximeter parameters to enable measurement of Oxyhemoglobin (SpO<sub>2</sub>), Carboxyhemoglobin (SpCO), Methemoglobin (SpMet) and Total Hemoglobin (SpHb). Rainbow sensors will only function with instruments containing Masimo Rainbow SET Technology or licensed to use Rainbow compatible sensors.

### Rainbow Adhesive Sensors

Rainbow adhesive sensors must be used in conjunction with Rainbow PC cables.

- R1 25
- R 25
- R1 25L
- R 25L
- R1 20
- R 20
- R1 20L
- R 20L

### Rainbow ReSposable™ Pulse CO-Oximeter Sensor System

The Rainbow ReSposable Sensors are used as a system.

- R2-25a with R2-25r
- R2-20a with R2-20r

### Rainbow Reusable Sensors

Rainbow Reusable sensors must be used in conjunction with Rainbow RC cables.

- DCI
- DCIP
- DCI SC-360
- DCIP SC-360

### Rainbow Direct Connect Sensors

Rainbow Direct Connect sensors connect to the instrument directly.

- DCI-dc3
- DCI-dc8
- DCI-dc12
- DCIP-dc3
- DCIP-dc8
- DCIP-dc12
- DC-3 SC360
- DC-12 SC360
- DCP-3 SC360
- DCP-12 SC360
- DC-3 SC200
- DCP-3 SC200

## Masimo Sensors (continued)

### MASIMO SPO<sub>2</sub> SENSORS

The Radical-7 may use standard Masimo LNOP, LNOPv and LNCS SpO<sub>2</sub> sensors, when used with Red PC or Red LNC Patient Cables respectively. Select the appropriate patient cable to attach the LNOP or LNCS sensor to the instrument.

### ReSposable™ Pulse CO-Oximeter Sensor System

The Rainbow ReSposable Sensors are used as a system.

- S2-25a with S2-25r
- S2-20a with S2-20r

### Red Direct Connect Sensors

Masimo Red sensors can be used with the Radical-7 to enable measurement of SpO<sub>2</sub> and pulse rate only. Red sensors will only function with Pulse CO-Oximeter instruments equipped with Masimo Rainbow SET technology. Red Direct Connect sensors connect to the instrument directly.

- DC-3
- DC-12
- DCP-3
- DCP-12

### LNOP® Reusable Sensors

LNOP sensors must be used in conjunction with Red PC cables.

- DCI
- DCIP
- YI
- TC-I
- DC-195
- TF-I

### LNOP® Adhesive Sensors

LNOP sensors must be used in conjunction with Red PC cables.

- Adt/Adtx
- Pdt/Pdtx
- Inf
- Neo
- NeoPt

### LNOPv™ Adhesive Sensors

LNOPv sensors must be used in conjunction with Red PC cables.

- In
- Ne
- Ad

## **Masimo Sensors (continued)**

### **LNOP® Specialty Sensors**

LNOP sensors must be used in conjunction with Red PC cables.

- Newborn Infant/Pediatric
- Newborn Neonatal
- Trauma
- Blue

### **M-LNCST™/LNCS® Reusable Sensors**

LNCS sensors must be used in conjunction with LNC cables.

- DCI
- DCIP
- YI
- TC-I
- TF-I

### **M-LNCST™/LNCS® Adhesive Sensors**

LNCS sensors must be used in conjunction with Red LNC cables.

- Adtx
- Pdtx
- Inf
- Neo
- NeoPt
- NeoPt-500

### **M-LNCST™/LNCS® Specialty Sensors**

LNCS specialty sensors must be used in conjunction with Red LNC cables.

- Newborn Infant/Pediatric
- Newborn Neonatal
- Trauma

## **SENSOR ACCURACY**

See Sensor Directions for Use (DFU) for sensor accuracy specifications for: SpO<sub>2</sub>, SpMet, SpCO, SpHb, and pulse rate.

## **CLEANING AND REUSE OF MASIMO REUSABLE SENSORS AND CABLES**

Reusable sensors and patient cables can be cleaned per the following procedure:

1. Remove the sensor from the patient.
2. Disconnect the sensor from the patient cable.
3. Disconnect the patient cable from the monitor.
4. Wipe the entire sensor and/or patient cable clean with a 70% isopropyl alcohol pad.
5. Allow to air dry thoroughly before returning it to operation.

**CAUTION:** CAREFULLY ROUTE PATIENT CABLES TO REDUCE THE POSSIBILITY OF PATIENT ENTANGLEMENT OR STRANGULATION.

## Masimo Sensors (continued)

### REATTACHMENT OF SINGLE USE ADHESIVE SENSORS

Single use sensors may be reapplied to the same patient if the emitter and detector windows are clear and the adhesive still adheres to the skin.

**NOTE:** *If the sensor fails to track the pulse consistently, the sensors may be incorrectly positioned. Reposition the sensor or choose a different monitoring site.*

**CAUTION:** DO NOT ATTEMPT TO REPROCESS, RECONDITION OR RECYCLE ANY MASIMO SENSORS OR PATIENT CABLES AS THESE PROCESSES MAY DAMAGE THE ELECTRICAL COMPONENTS, POTENTIALLY LEADING TO PATIENT HARM.

**CAUTION:** TO PREVENT DAMAGE, DO NOT SOAK OR IMMERSE THE SENSOR IN ANY LIQUID SOLUTION. DO NOT ATTEMPT TO STERILIZE BY IRRADIATION, STEAM, AUTOCLAVE OR ANY METHOD OTHER THAN ETHYLENE OXIDE AS INDICATED.

WARNING: TO AVOID CROSS CONTAMINATION ONLY USE MASIMO SINGLE USE SENSORS ON THE SAME PATIENT.





## Introduction

This section covers:

- How to test the operation of the Radical-7 Pulse CO-Oximeter and the SatShare interface.
- How to properly clean the Radical-7 Pulse CO-Oximeter.
- How to recharge and replace the batteries.
- How to replace the fuses.
- How to obtain service.

Under normal operation, no internal adjustment or recalibration is required. Safety tests and internal adjustments should be done by qualified personnel only. Safety checks should be performed at regular intervals or in accordance with local and governmental regulations.

**WARNING: ELECTRICAL SHOCK AND FLAMMABILITY HAZARD - BEFORE CLEANING THE PULSE CO-OXIMETER, ALWAYS TURN IT OFF AND DISCONNECT THE POWER CORD FROM THE AC POWER SUPPLY.**

The Masimo Rainbow SET<sup>®</sup> Radical-7 Pulse CO-Oximeter is a reusable instrument. The instrument is supplied and used non-sterile.

## Cleaning

The outer surface of the Masimo Rainbow SET<sup>®</sup> Radical-7 Pulse CO-Oximeter can be cleaned with a soft cloth dampened with a mild detergent and warm water solution. Do not allow liquids to enter the interior of the instrument. The outer surface of the instrument can also be wiped down using the following solvents: Cidex Plus (3.4% Glutaraldehyde), 10% Bleach, and 70% Isopropyl Alcohol.

- DO NOT AUTOCLAVE, PRESSURE STERILIZE, OR GAS STERILIZE THE PULSE CO-OXIMETER.
- DO NOT SOAK OR IMMERSE THE PULSE CO-OXIMETER IN ANY LIQUID.
- USE THE CLEANING SOLUTION SPARINGLY. EXCESSIVE SOLUTION CAN FLOW INTO THE PULSE CO-OXIMETER AND CAUSE DAMAGE TO INTERNAL COMPONENTS.
- DO NOT TOUCH, PRESS, OR RUB THE DISPLAY PANELS WITH ABRASIVE CLEANING COMPOUNDS, INSTRUMENTS, BRUSHES, ROUGH-SURFACE MATERIALS, OR BRING THEM INTO CONTACT WITH ANYTHING THAT COULD SCRATCH THE PANEL.
- DO NOT USE PETROLEUM-BASED OR ACETONE SOLUTIONS, OR OTHER HARSH SOLVENTS, TO CLEAN THE PULSE CO-OXIMETER. THESE SUBSTANCES ERODE THE INSTRUMENT'S MATERIALS AND INSTRUMENT FAILURE CAN RESULT.

Refer to Section 8, *Cleaning and Reuse of Masimo Sensors* for cleaning instructions of the sensor.

## Battery Operation and Maintenance

The Radical-7 Pulse CO-Oximeter Handheld includes a 1.5 Amp-Hour Nickel Metal Hydride battery. The Radical-7 Pulse CO-Oximeter Docking Station may include the optional 6.5 Amp-Hour Nickel Metal Hydride battery.

Before using the Radical-7 Pulse CO-Oximeter as a Handheld or transport monitor, the Handheld battery and the optional Docking Station battery need to be fully charged.

To charge the battery(s), attach the Handheld instrument to the Docking Station. Ensure that AC power is attached to the Docking Station. Verify that the battery(s) is charging; the battery charging LED indicators on the Docking Station flash prior to charging and remain illuminated while the battery(s) is charging. A continuously flashing battery charging LED indicates that the internal battery temperature exceeds recommended operating conditions for proper battery charging. Proper battery charging will proceed when the temperature returns to recommended operating conditions.

The Handheld battery requires approximately 2 to 3 hours for charging. The optional Docking Station battery requires approximately 6 hours for charging.

When the battery charging LED indicators turn off, additional trickle charging may occur to complete charging. Although battery charging can occur while the Handheld is docked and powered on, most efficient charge times are achieved with the Handheld instrument turned off.

### CAUTIONS:

- ALL BATTERIES LOSE CAPACITY WITH AGE, THUS THE AMOUNT OF RUN TIME LEFT AT LOW BATTERY WILL VARY DEPENDING UPON THE AGE OF THE BATTERY.
- AT LOW BATTERY CONNECT THE RADICAL-7 PULSE CO-OXIMETER TO AC POWER TO PREVENT LOSS OF POWER.

During battery operation of the Radical-7 Pulse CO-Oximeter, please note that the following operating conditions affect the estimated run-time of the included batteries:

- ILLUMINATION OF THE BACKLIT LCD SCREEN. TO CONSERVE BATTERY POWER, KEEP THE BACKLIT LCD SCREEN AT MINIMUM ILLUMINATION.
- VOLUME OF THE ALARM TONES. TO CONSERVE BATTERY POWER, KEEP THE FREQUENCY OF THE AUDIBLE ALARMS TO A MINIMUM AND AT MINIMUM VOLUME.
- THE SATSHARE FEATURE. TO CONSERVE BATTERY POWER, ALWAYS KEEP THE INSTRUMENT ON AC LINE POWER.

Memory effects of the battery pack may shorten run-time. When battery run-time is significantly reduced, it is advisable to completely discharge and fully recharge the battery pack. To properly discharge the battery pack, use the Battery Discharge function as described in Section 4, under *Service*.

### CAUTION:

- IF THE RADICAL-7 PULSE CO-OXIMETER HANDHELD HAS NOT BEEN USED OR CHARGED WITHIN SEVEN (7) DAYS OR MORE, THEN RECHARGE THE BATTERY PRIOR TO USE.
- IT IS RECOMMENDED THAT THE RADICAL-7 PULSE CO-OXIMETER HANDHELD IS DOCKED TO THE DOCKING STATION ATTACHED TO AN AC POWER SOURCE WHEN IT IS NOT IN USE TO ENSURE THAT THE BATTERY REMAINS FULLY CHARGED.

## Battery Operation and Maintenance (continued)

The following tables outline the estimated run times of the battery powered Radical-7 Pulse CO-Oximeter. The time estimates are based on a Radical-7 Pulse CO-Oximeter with fully charged batteries. The time estimates are also based on a Radical-7 with and without the backlight lit, and the power save feature enabled and disabled.

The Radical-7 Pulse CO-Oximeter is always configured to include the Handheld battery. It may optionally be configured to include the Docking Station battery. Please determine the configuration of your system before referencing the following tables.

### CONFIGURATION #1:

Radical-7 Pulse CO-Oximeter configured to only include the Handheld battery (standard configuration); the Docking Station battery is excluded.

**NOTE:** For this configuration, it is advisable to operate only the Radical-7 Handheld instrument when running on battery power. Although it is possible to operate the entire Standalone instrument (the Handheld attached to the Docking Station, with the Handheld battery powering the Docking Station as well) on battery power, the capacity of the Handheld battery pack is insufficient to support this mode for long periods of time. The Power Save setting in the General menu determines whether the Docking Station is powered or not during battery operation. See Section 4, General, for a detailed description on proper use of the Power Save setting.

RADICAL-7 CONFIGURATION	OPERATION MODE	MINIMUM RUN-TIME
HANDHELD ONLY	Power Save "yes" Backlight turned "off"	4 hrs
HANDHELD ONLY	Power Save "no" Backlight turned "on"	1 hr

### CONFIGURATION #2:

Radical-7 configured to include the Handheld and the Docking Station battery:

RADICAL-7 CONFIGURATION	OPERATION MODE	MINIMUM RUN-TIME
HANDHELD AND DOCKING STATION	Power Save "yes" Backlight turned "off"	10 hrs
HANDHELD AND DOCKING STATION	Power Save "no" Backlight turned "on"	6 hr

## REPLACING THE BATTERIES

Before installing or removing the battery, make sure the AC power cord is removed and power to the Pulse CO-Oximeter is turned off.

To replace the Handheld battery, follow these instructions:

1. Turn the Radical-7 Pulse CO-Oximeter Handheld off and remove the patient cable connection. Detach the Radical-7 Pulse CO-Oximeter Handheld from the Docking Station (if docked).
2. Loosen the closure screw on the battery compartment door and lift out the battery.
3. Take a new battery, and place it in the compartment.
4. Tighten the closure screw.
5. Place Handheld into Docking Station, turn on line power and charge battery according to this Section, Battery Operation and Maintenance.

**CAUTION:** FOLLOW LOCAL GOVERNING GUIDELINES FOR PROPER DISPOSAL OF INTERNAL BATTERIES. DO NOT INCINERATE.

**WARNING:** THE DOCKING STATION BATTERY SHOULD BE INSTALLED AND/OR REMOVED FROM DOCKING STATION BY QUALIFIED PERSONNEL ONLY.

## REPLACING THE FUSES

Should a power problem blow one or both of the fuses in the power entry module on the rear panel, the fuse(s) will need to be replaced.

To replace the fuse(s), you will need a flat-blade screwdriver (5mm; 3/16").

To replace the fuses:

1. Disconnect instrument from AC power.
2. Remove AC power cord from the power entry module at the rear of the docking station.
3. Use the small flat-blade screwdriver and gently pry loose the fuse cover in the left portion of the power entry module, exposing the fuse holder.
4. Using the small flat-blade screwdriver, gently remove the fuse holder.
5. Note how the fuse(s) are placed in the fuse holder for installation of the new fuse(s).
6. To remove the fuses from the fuse holder, use the edge of the screwdriver blade to pry against the bottom of the metal portion of the fuse where it is secured to the glass portion of the fuse.
7. Place the fuse(s) (1 Amp, Metric, fast acting, 5x20mm, 250V) in the fuse holder, properly orienting the fuse(s).
8. Slide the fuse holder back into the power entry module and press firmly to make sure it is completely seated.
9. Close the fuse cover and press gently until it seats completely, flush with the back of the docking station.
10. The instrument is ready to be reconnected to AC power.

**NOTE:** If the fuses blow shortly after replacement, the instrument requires service.

**WARNING:** FIRE HAZARD: TO PROTECT AGAINST FIRE HAZARD, REPLACE ONLY WITH FUSES OF THE SAME TYPE, CURRENT RATING, AND VOLTAGE RATING.

## Performance Verification

To test the performance of the Radical-7 Pulse CO-Oximeter following repairs or during routine maintenance, follow the procedure outlined in this section. If the Radical-7 Pulse CO-Oximeter fails any of the described tests, discontinue its use and correct the problem before returning the instrument back to the user.

Before performing the following tests place the Radical-7 Pulse CO-Oximeter Handheld into the Docking Station, connect the Radical-7 to AC power and fully charge the Radical-7 Pulse CO-Oximeter Handheld battery. Also disconnect any patient cables or pulse oximetry probes, as well as SatShare, serial or analog output cables from the instrument. Set the Radical-7 Pulse CO-Oximeter to normal operating mode by selecting the Home Use parameter in the General Menu to "No".

### Power-On Self-Test:

1. Connect the monitor to AC power and verify that the AC Power Indicator is lit.
2. Turn the monitor on by depressing the Power/Standby Button. Within 5 seconds all available LEDs are illuminated, a 1-second beep tone sounds, and the Masimo SET logo is displayed.
3. The blue Docking Indicator LED is illuminated and the Radical-7 begins normal operation.

### Key Press Button Test:

With the exception of the Power/Standby Button, press each soft key button and verify that the Radical-7 acknowledges each key-press with an audible beep tone or by indicating a change on the display.

### Alarm Limit Test:

1. With the monitor turned on, select the Menu Access key and enter the Alarm menu. Change the High SpO<sub>2</sub> Alarm parameter to a value two points below the currently selected value, and accept the change.
2. Verify that the newly set parameter is shown on the Saturation Alarm Limit Display, next to the SpO<sub>2</sub> or pulse rate measurement display.
3. Return the High Saturation Alarm parameter to its original setting.
4. Repeat steps 1 to 3 for the following alarm parameters:
  - Low SpO<sub>2</sub>
  - High and Low Pulse Rate
  - High SpMet
  - High SpCO
  - High and Low SpHb
5. Reset the alarm limits again to the original settings.

### Display Contrast Test:

1. With the monitor turned on, select the Menu Access key and enter the Display menu. Change the Contrast parameter by scrolling through the contrast settings.
2. Return the Contrast setting to the original value, or a value that allows maximum viewing contrast.
3. Exit the Menu system and press and hold down the Backlight/Contrast button for several seconds. The display will scroll again through all the contrast settings.
4. Release the Backlight/Contrast button again when the display shows maximum viewing contrast.

**Testing with Masimo SET Tester (Optional):**

1. Turn the Radical-7 off and then on again.
2. Connect the Masimo SET Tester to the Pulse CO-Oximeter Patient Cable Connector. Refer to the Masimo SET Tester's Directions for Use for further instructions.

**Nurse Call Test:**

1. Disconnect the Red patient cable or the Masimo SET Tester from the Radical-7 and turn the instrument on. Ensure that there are no audible alarms and that the audible alarms are not silenced. Verify the nurse call polarity is set to normal (default).
2. Connect the common lead of a digital multi-meter to the pin 12 (Nurse Call - Common) of the analog output connector on the Radical. Connect the positive lead of the multi-meter to pin 6 (Nurse Call - Normally Open) of the analog output connector and measure that the resistance is greater than 1 MW (open circuit).
3. Trigger an alarm on the monitor (e.g. by disconnecting a sensor after it was measuring data) and verify that the resistance is less than 35 ohms.

**Analog Output Test:**

1. Disconnect all patient cables and sensors from the Radical-7. Turn the Radical-7 off and then on again.
2. Connect the common lead of a digital voltmeter to the pin 2 (Ground) of the analog output connector on the Radical-7. Connect the positive lead of the voltmeter to pin 9 (Analog 1) of the analog output connector.
3. Enter the menu system and set the "Output", "Analog 1" to "0V Signal". Verify that the voltmeter measures a voltage of approximately 0V.
4. Enter the menu system and set the "Output", "Analog 1" to "1V Signal". Verify that the voltmeter measures a voltage of approximately 1.0V.
5. Repeat Steps 3 and 4, with the positive lead of the voltmeter connected to pin 15 (Analog 2).
6. Connect a patient cable and sensor and verify that the voltage on pins 9 and 15 are between 0V and 1.0V while measuring a saturation and pulse rate.

**Battery Test:**

1. Fully charge the Radical-7 by placing the Handheld into the Docking Station and connecting the AC power.
2. Verify that the green Handheld Battery Indicator LED is illuminated.
3. When the Radical-7 is fully charged the green Handheld Battery Indicator turns off.
4. Turn the Radical-7 on and verify that the Battery indicator shows a full charge.

## Service and Repair

### REPAIR POLICY

Masimo or an authorized Service Department must perform warranty repair and service. Do not use malfunctioning equipment. Have the instrument repaired.

**WARNING:** DO NOT REMOVE THE COVER OF THE MONITOR EXCEPT FOR BATTERY REPLACEMENT. AN OPERATOR MAY ONLY PERFORM MAINTENANCE PROCEDURES SPECIFICALLY DESCRIBED IN THIS MANUAL. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL TRAINED IN THE REPAIR OF THIS EQUIPMENT.

Please clean contaminated and/or dirty equipment before returning, following the cleaning procedure described in Section 9, *Cleaning*. Make sure the equipment is fully dry before packing.

To return the Radical-7 instrument for service, please follow the Return Procedure.

### RETURN PROCEDURE

Please clean contaminated/dirty equipment before returning. Make sure the equipment is fully dry before packing. Call Masimo at 800-326-4890 and ask for Technical Support. Ask for an RMA number. Package the equipment securely – in the original shipping container if possible – and enclose or include the following information and items:

- A letter describing in detail any difficulties experienced with the Pulse CO-Oximeter. Please include the RMA number in the letter.
- Warranty information – a copy of the invoice or other applicable documentation must be included.
- Purchase order number to cover repair if the Pulse CO-Oximeter is not under warranty, or for tracking purposes if it is.
- Ship-to and bill-to information.
- Person (name, telephone/Telex/fax number, and country) to contact for any questions about the repairs.
- A certificate stating the Pulse CO-Oximeter has been decontaminated for bloodborne pathogens.

Return Radical-7 Pulse CO-Oximeter to the following shipping address:

For USA, Canada & Asia Pacific:	For Europe:	All other locations:
Masimo Corporation 304 Parker Irvine, California 92618 949-297-7000 FAX 949-297-7001	Masimo Europe Limited 304 RN6, Le Bois des Cotes 2 69760 Limonest France	Contact your local Masimo Representative.

## Warranty

Masimo warrants to the initial Purchaser for a period of one (1) year from the date of purchase that: (i) each new Product and the Software media as delivered are free from defects in workmanship or materials, and (ii) the Product and Software will perform substantially as labeled in the directions for use. Masimo's sole obligation under this warranty is to repair or replace any Product or Software that is covered under warranty.

Batteries are warranted for six (6) months.

To request a replacement under warranty, Purchaser must contact Masimo for a returned goods authorization. If Masimo determines that a Product must be replaced under warranty, it will be replaced and the cost of shipment covered. All other shipping costs shall be the responsibility of Purchaser.

## Exclusions

The warranty does not extend to, and Masimo is not responsible for, repair, replacement, or maintenance needed because of: a) modification of the Product or Software without Masimo's written authorization; b) supplies, instruments or electrical work external to the Product or not manufactured by Masimo; c) disassembly or reassembly of the Product by anyone other than an authorized Masimo agent; d) use of the Product with sensors or other accessories other than those manufactured and distributed by Masimo; e) use of the Product and Software in ways or in environments for which they are not labeled; and f) neglect, misuse, improper operation, accident, fire, water, vandalism, weather, war, or any act of God. This warranty does not extend to any Product that has been reprocessed, reconditioned or recycled.

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PART NUMBER	DESCRIPTION
2386	REPLACEMENT BATTERY, RADICAL-7 HANDHELD
1317	RADICAL-7 POLE CLAMP
2350	RADICAL-7 HANDHELD LOCK
2351	RADICAL-7 HANDHELD LOCK KEY
2368	MASIMO SET TESTER - 20 PIN
1584	RADICAL-7 POWER CORD LOCK, 5/PACK
1908	TRENDCOM SOFTWARE
1595	SATSHARE CABLE, AT01
1324	SATSHARE CABLE, DO01
1326	SATSHARE CABLE, DO02
1528	SATSHARE CABLE, DO03
1533	SATSHARE CABLE, DO04
2023	SATSHARE CABLE, DO05
1325	SATSHARE CABLE, DS01
1539	SATSHARE CABLE, DS02
1528	SATSHARE CABLE, DS03
1357	SATSHARE CABLE, HP03
1321	SATSHARE CABLE, MQ01
1789	SATSHARE CABLE, MS01
1367	SATSHARE CABLE, NK01
1368	SATSHARE CABLE, NK02
1366	SATSHARE CABLE, OH01
1646	SATSHARE CABLE, OH02
1840	SATSHARE CABLE, PM01
1323	SATSHARE CABLE, SL01
1362	SATSHARE CABLE, SL02
1322	SATSHARE CABLE, SM01
1605	SATSHARE EXTENSION CABLE
32218	RADICAL-7 OPERATOR'S MANUAL - ENGLISH
32760	RADICAL-7 OPERATOR'S MANUAL - FRENCH
32761	RADICAL-7 OPERATOR'S MANUAL - GERMAN
32762	RADICAL-7 OPERATOR'S MANUAL - ITALIAN
32763	RADICAL-7 OPERATOR'S MANUAL - SPANISH
32768	RADICAL-7 OPERATOR'S MANUAL - SWEDISH
32765	RADICAL-7 OPERATOR'S MANUAL - DUTCH
32767	RADICAL-7 OPERATOR'S MANUAL - DANISH
32766	RADICAL-7 OPERATOR'S MANUAL - PORTUGUESE
32769	RADICAL-7 OPERATOR'S MANUAL - CHINESE
30475	RADICAL-7 HANDHELD CASE

Please visit our website, [www.masimo.com](http://www.masimo.com), for updated information about accessories.



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Instruments and sensors containing Masimo Rainbow SET technology are identified with the Masimo Rainbow SET logo.

